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An Innovative Clinical Evaluation Protocol after Total Ankle Arthroplasty: A Pilot Study Using Inertial Sensors and Baropodometric Platforms

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Abstract: Background: Total ankle arthroplasty (TAA) has grown in popularity and indications, with encouraging results over time. Today, preoperative and postoperative evaluations are mainly performed using clinical test and diagnostic imaging, but there is a deficiency in objectively evaluating the biomechanics of the foot and ankle, which serve as the functional markers for monitoring the effectiveness and outcomes of surgery. Inertial measurement units associated with plantar pressure measurements may provide an accurate and reliable method of evaluating function through the analysis of gait and ankle joint mobility. The aim of this study was to introduce an innovative technology, to assess its accuracy and feasibility compared to standard clinical assessment methods and to objectify kinematic outcomes in patients with end-stage ankle OA before and after TAA surgery. Methods: A consecutive series of eight patients with symptomatic end-stage osteoarthritis and treated with TAA was prospectively evaluated using clinical scores (AOFAS, MOxFQ, VAS, SF-36, 17-IFFI), physical tests (FPI, ALT), plantar pressure measurements with FLEX EPS/R2 Letsense® baropodometric platform, gait analysis and wearable sensors-based ankle motion and kinematic outcomes using Wiva Science inertial sensors by Letsense®. Data were collected preoperatively and 4 months after surgery. Results: All PROMs exhibited statistical significance in improvement from pre- to postoperative periods, except for one. Physical examinations showed no significant changes of the foot shape and alignment. Plantar pressure analyses revealed no significant changes in static and dynamic evaluations, but a more uniform distribution of plantar pressure was observed between the two periods. Inertial sensor parameters demonstrated no significant differences, except for a significant reduction in stride length and step length for the operated foot after surgery. Conclusions: Gait analysis using inertial sensors and plantar pressure measurements offer ease of handling, cost effectiveness, portability and swift data reading, making them highly appealing for widespread clinical use. Integrating these tools into the routine assessments of patients with TAA holds promise for advancing precision of treating this condition and our depth of its understanding, contributing to more comprehensive and insightful patient care.

Keywords: gait analysis; inertial sensors; total ankle arthroplasty

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1. Introduction

End-stage ankle osteoarthritis (OA) is a severely disabling chronic disease, causing pain and functional impairment [1–4]. It often causes ankle joint deformities; modifies foot and ankle physiological biomechanics; and develops a compensatory gait pattern [5]. In this condition, the contralateral foot bears an abnormal load during dynamic activities and therefore an asymmetrical gait pattern occurs [6–11].

In the case of symptomatic end-stage OA, surgery is indicated [4,12]. Currently, the main two options for the treatment of end-stage OA [12,13] are represented by ankle arthrodesis (AA) and total ankle arthroplasty (TAA).

AA consists of the tibio-talar joint fusion, and it has been the gold-standard treatment for many years [14,15]. TAA [16] has been proposed in order to preserve a physiological gait and reduce the chance of secondary arthritis of nearby articulations. Recently, TAA has grown in popularity and indications, with encouraging results over time [12,17,18].

To date, preoperative and postoperative evaluations are mainly performed using clinical tests and diagnostic imaging. However, these methods do not objectively assess the biomechanics of the foot and ankle, which should serve as functional indicator for monitoring the effectiveness and outcomes of surgery. Recent technological developments ensure that health figures and orthopedists acquire new tools for validating surgical treatment in a more objective way. Thanks to the inertial sensors with a dedicated protocol, it was possible to detect function-specific movements to assess the state of the ankle biomechanics, allowing orthopedic surgeons to better understand the clinical and kinematics outcomes. Despite this, studies reporting gait analysis characteristics in patients treated for TAA are rare in the literature because in vivo gait analysis is rarely performed due to the tools' cost and complicated usage, while innovative inertial sensors are cheap and easy to use. Moreover, the current routine in clinical practice is to measure the ankle joint angle with a universal goniometer, but this measurement highly depends on a clinician's expertise and has poor inter- and intra-rater reliability [19]. Alternatively, the method of assessing range of motion (ROM) using radiographs, as described in the literature, may be compromised by the fact that joint movements at maximum degrees are passive and may differ from physiological ROM during gait [20]. Inertial sensors measurement may provide an accurate and reliable method of active joint ROM assessments and to overcome the poor inter-rater and intra-rater reliability of goniometric ankle measurements.

The main focus of this study was to achieve greater insight into postoperative TAA evaluations. In particular, the aim was to introduce an innovative technology; to assess its accuracy and feasibility compared to standard clinical assessment methods; and to objectify kinematic outcomes in patients with end-stage ankle OA before and after TAA surgery.

2. Materials and Methods

2.1. Study Design and Participants

After obtaining ethical approval from the authors' institution's ethics committee, a prospective observational study was conducted. All patients with symptomatic end-stage OA and treated for TAA between January 2020 and December 2021 were enrolled.

In accordance with the Declaration of Helsinki, informed consent of all patients was collected before the evaluations. The patients were extensively informed about this study and the clinical evaluations before and after surgery.

2.2. Patient Selection

In this study, all patients with a diagnosis of symptomatic end-stage ankle OA who underwent TAA were included. All patients were over 18 years old and included only patients with a minimum of 2 months follow up, while patients with BMI > 30 mg/m^2, deambulatory anomalies (amputations, neuro-muscular disorders, cognitive deficits, poliomyelitis, hip dysplasia), or severe postural instability were excluded. Two independent researchers collected all clinical data from the patients.

2.3. Clinical Evaluation

Each patient was administered a patient-related outcome measure (PROM) questionnaire the day before the surgery.

The clinical PROMs were as follows:

- The American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Score (AOFAS-AHES) [21–23].
- The Manchester–Oxford Foot Questionnaire (MOxFQ) [24].
- The Visual Analogue Scale (VAS) [25].
- The Short-Form Health Survey (SF-36) [26].
- 17-Italian Foot Function Index (17-IFFI) [27].

The clinical evaluation serves as a benchmark for postoperative functional assessment outcomes, providing a standard reference for comparison with results obtained from innovative tools.

2.4. Physical Examination

Each patient was examined the day before surgery for the assessment of the Foot Posture Index (FPI) [28] (Table 1) and the Ankle Lunge Test (ALT) [29] (Figure 1).

Table 1. FPI classifies foot posture according to six items. Each item is scored from −2 to 2, resulting in a total score of −12 to 12. Negative values indicate supinated foot posture and positive values indicate pronated foot posture.

Rearfoot Score	**−2**	**−1**	**0**	**1**	**2**
Talar head palpation	Talar head palpable on lateral side/but not on medial side	Talar head palpable on lateral side/slightly palpable on medial side	Talar head equally palpable on lateral and medial side	Talar head slightly palpable on lateral side/palpable on medial side	Talar head not palpable on lateral side/but palpable on medial side
Curves above and below the malleoli	Curve below the malleolus either straight or convex	Curve below the malleolus concave, but flatter/shallower than the curve above the malleolus	Both infra and supra malleolar curves roughly equal	curve below malleolus more concave than curve above malleolus	Curve below malleolus markedly more concave than curve above malleolus
Calcaneal inversion/eversion	More than an estimated 5° inverted (varus)	Between vertical and an estimated 5° inverted (varus)	Vertical	Between vertical and an estimated 5° everted (valgus)	More than an estimated 5° everted (valgus)
Forefoot Score	**−2**	**−1**	**0**	**1**	**2**
Talo-navicular congruence	Area of TNJ markedly concave	Area of TNJ slightly, but definitely concave	Area of TNJ flat	Area of TNJ bulging slightly	Area of TNJ bulging markedly
Medial arch height	Arch high and acutely angled towards the posterior end of the medial arch	Arch moderately high and slightly acute posteriorly	Arch height normal and concentrically curved	Arch lowered with some flattening in the central portion	Arch very low with severe flattening in the central portion—arch making ground contact
Forefoot ab/adduction	No lateral toes visible. Medial toes clearly visible	Medial toes clearly more visible than lateral	Medial and lateral toes equally visible	Lateral toes clearly more visible than medial	No medial toes visible. Lateral toes clearly visible

Figure 1. Ankle Lunge Test (ALT). The patient positions their foot perpendicular to the wall and brings their knee towards it. The foot is then gradually moved away from the wall until the maximum ankle dorsiflexion is achieved without lifting the heel. The distance between the foot and the wall, reported in cm, and the angle of the tibial shaft from the vertical, reported in degrees (°), was then measured.

2.5. Plantar Pressure and Gait Analysis

The ankle and foot functionality was analyzed pre- and postoperatively through baropodometric platform and inertial sensors.

2.5.1. Baropodometric Platform

The baropodometer is a platform used to analyze plantar pressure distribution in both a static and dynamic position. A software elaborate data from static and weight-bearing plantar pressure distribution during gait (dynamic baropodometry). For this study, the flexible baropodometric platform model FLEX EPS/R2 by Letsense® (Letsense group, Bologna, Italy) was used [30].

This platform consists of 2304 resistive sensors, and the platform's active surface measures 48 × 48 cm^2 and is formed by a conductive polymer layer, where sensors are arranged in matrix form. The results are displayed and analyzed using Biomech Studio 2018® software for Windows.

In the static examination, the patient climbed on the platform, looked at a fixed point ahead and slightly spread the feet. The feet were placed parallel to each other, spaced about should-width apart. The patient emptied their pockets from any objects that they had and/or any accessories they had on the arms/wrists before stepping on the platform to not impair weight distribution. The patient maintained an upright posture for 30 s (the duration varies depending on the type of patient and data needed to be analyzed). In this orthostatic measurement, the following parameters were evaluated:

- Load distribution [%] (Figure 2): indicates the load distribution between the feet.
- Total anteroposterior load distribution [%] (Figure 2): indicates the load distribution between the hindfoot and forefoot of both feet. Normal reference values: 40–45% in forefoot; 55–60% in hindfoot.

- Mean pressure [kPa] (Figure 2): indicates the average plantar pressure recorded in each foot. This parameter is improved with the reduction in the difference between the mean pressure values of the operated foot and the non-operated foot. The reference scale considered ranges from 0 to 500 kPa.
- Peak pressure [position, kPa]: indicates the point on the foot where the maximum pressure value is recorded, with the maximum value associated.
- Ellipse area of the body's barycenter [mm^2] (Figure 2): indicates the movement of the barycenter and center of pressure (C.O.P.) of the two feet. The ellipse represents 90% of it.
- Ellipse area of the foot's barycenter [mm^2] (Figure 2): indicates the movement of the barycenter and center of pressure (C.O.P.) of the foot. The ellipse contains 90% of it.
- C.O.P. distance [mm] (Figure 2): indicates the average distance of the C.O.P. trajectory from the central point of the trajectory itself. The reduction of the elliptical surface of the body's barycenter, elliptical surface of the foot's barycenter and C.O.P. distance indicates a lower movement of the center of pressure and, therefore, a greater stability of the barycenter of the patient examined.

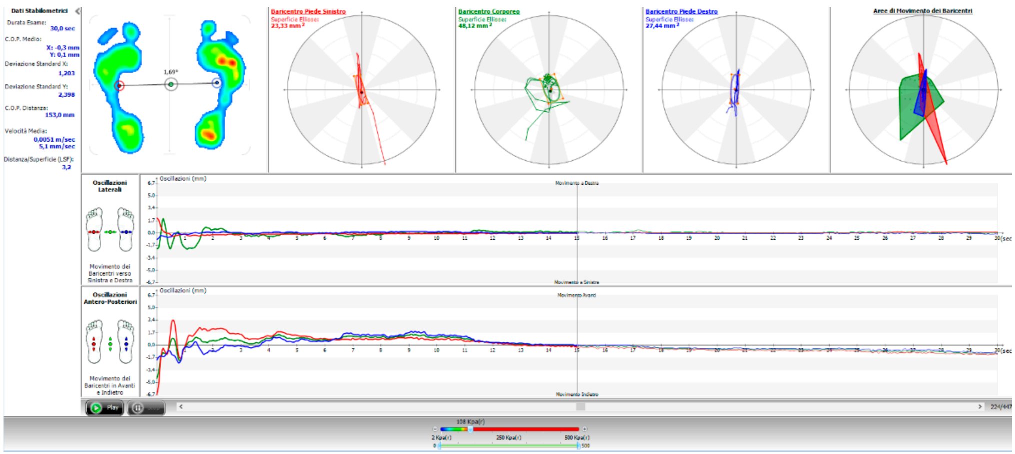

Figure 2. Graphical visualization of plantar pressure parameters shown in software.

In the dynamic examination, the patient walked forward and backward so that their third step was performed on the platform. Every foot was measured 6 times. Each parameter was recorded as a mean value using the aforementioned software. The main parameters reported by the software were as follows:

- Mean pressure [kPa]: indicates the average plantar pressure recorded in each foot. This parameter is improved with the reduction in the difference among the mean pressure values between the operated and non-operated foot. The reference scale considered ranges from 0 to 500 kPa.
- Peak pressure during gait [position, kPa]: indicates the point of the foot where the maximum pressure value is recorded at each step stage (contact phase, intermediate support phase, propulsion phase), with maximum associated value.
- Maximum load points curve: connects all the maximum load points at every moment of the step, in both feet. The normal course of this curve is represented by the normal pronation–supination movements that the foot performed during the gait.

2.5.2. Inertial Sensors

Inertial measurement units (IMUs) are small, lightweight sensors that consist of an accelerometer, gyroscope and magnetometer able to measure gait characteristics and to compute spatial-temporal and specific kinematic parameters.

The IMUs used in this study were Wiva Science IMUs by Letsense® (Letsense group, Bologna, Italy). A sensor was positioned on the patient's waist (L5 level) with a special belt that does not affect mobility; in this way, the patient could walk freely [10,31].

Ankle joint mobility measurements were performed with a sensor placed on the dorsum of the foot (II–IV metatarsal level). Joint range analysis was conducted passively by the operator with the patient sitting. At the end of the gait and joint mobility analysis, the parameters calculated during the tests were displayed to the software Biomech Studio 2018®.

The following parameters were evaluated:

- Walking speed [m/min], normal values: 77.4 m/min for men; 71.4 m/min for women [32].
- Cadence [steps/min]—number of steps per minute, normal values: 52.8 steps/min for men; 55.8 steps/min for women [32].
- Stride length [m]—distance between two consecutive heels strikes of the same foot, normal values: 1.46 m for men; 1.28 m for women [32].
- Stride duration [s]—the time between two consecutive heel strikes of the same foot, normal values: 1.14 (±0.08) s for men; 1.08 (±0.08) s for women [32].
- Step length [m]—between the ipsilateral and contralateral heel strikes. The parameter is expressed as a percentage value considering the stride length; normal values: 50% left; 50% right [32].
- Step duration [s]—the time between ipsilateral and contralateral heel strikes. The parameter is expressed as a percentage value considering the duration of the step cycle (symmetry ratio); normal values: 50% left; 50% right [32].
- Stance duration [% of gait cycle]—the foot support phase, i.e., from heel strike to toe off of the same foot, duration as percentage of gait cycle, normal values: 60.31 (±1.7)% [32].
- Swing duration [% of gait cycle]—the foot swing phase, i.e., from toe-off to heel strike of the same foot, duration as percentage of gait cycle, normal values: 39.6 (±1.9)% [32].
- Double support duration [%]—the duration of the phase of support on both feet as percentage of gait cycle, normal values: 9.4 (±2.3)% for men; 9.6 (±4.6)% for women [32].
- Variability [% of the affected foot gait duration]—the coefficient variation in the duration of the gait of the foot considered. Indicates the reproducibility/repeatability of a step-in time; the lower the value, the more the step is repeatable. Therefore, it undergoes fewer variations during the cycle of the walk.
- Symmetry—the ratio between the swing duration of the right foot and the swing duration of the left foot. It is an index used to evaluate the difference between the two steps during the gait. The ratio of maximum symmetry is when the index is equal to 1.

The trunk or pelvis movements' kinematic data are presented on the sagittal, frontal and transverse planes, and are defined, respectively, as tilt angle, obliquity and rotation.

- TILT (sagittal plane) [°] (Figure 3) is defined as the rotation of the pelvis around its transverse axis. The angle is defined as positive of anterior bending and negative the rear bending.
- OBLIQUITY (frontal plane) [°] (Figure 3): on the frontal plane each "hemi-pelvis" rises during the support phase (stance) and descends in the swing phase of the corresponding leg. Positive angle values (Up) are defined with the lifting of the right pelvis during foot support of the corresponding foot, while negative angle values (Down) are defined with the lowering of the right pelvis resulting in lifting the left pelvis during support of the corresponding foot.
- ROTATION (transverse plane) [°] (Figure 3): each "hemi-pelvis" rotates internally to the side of the dominant leg. Observing the pelvis from above and from the point of view of the analyzed subject, the angle of rotation provided by Biomech is defined as a positive rotation when the right side of the body advances (right internal rotation) and the left side retreats (left outer rotation); it is negative when the left side of the body advances (left internal rotation) and the right side retreats (right external rotation).

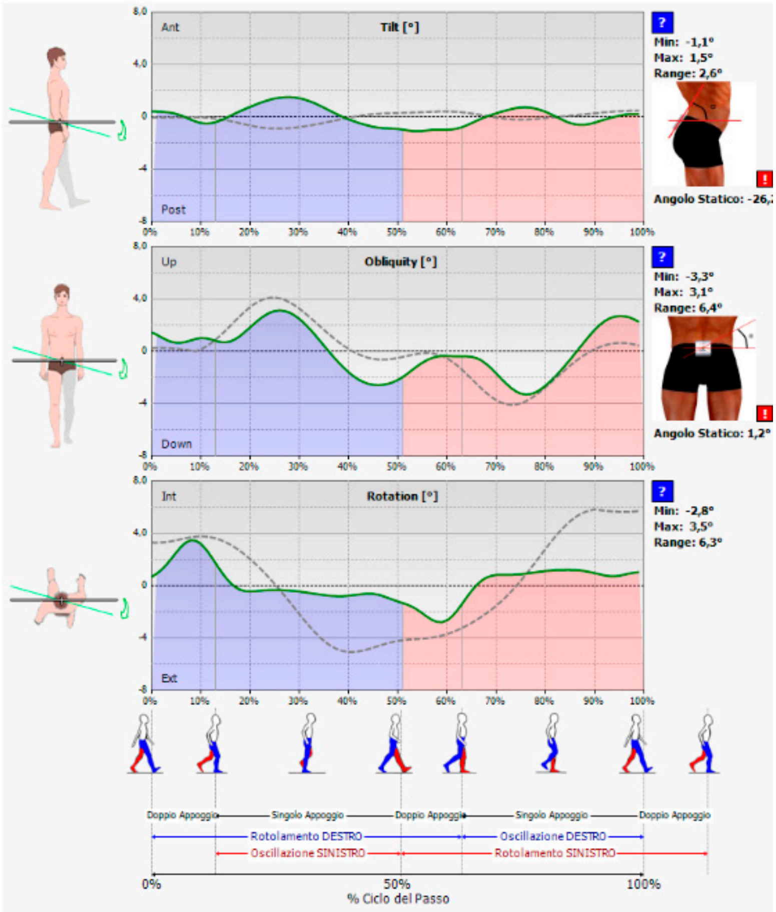

Figure 3. Graphical representation of the trunk and pelvis movement during gait.

The anterior bending angles (tilt), left side inclination (obliquity) and right side rotation (rotation) are given as positive values, while the opposite movements are given as negative values. The final values were expressed as differences between the two movements, and a value close to 0 indicates a good pelvic/trunk balance.

The ankle joint ROM measurements with sensors in the sagittal plane (dorsal and plantar flexion) are evaluated. Normal values range from 10° up to 15°–25° for dorsal flexion and from 20° up to 45°–50° for plantar flexion.

2.6. Surgical Technique and Postoperative Management

TAA was performed through a 10 cm anterior approach to the ankle, exploiting the interval between the extensor hallucis longus and the anterior tibialis tendon until the bone was exposed. Cutting guides were placed relative to the anatomical tibial axis. Thus, using the oscillating bone saw, talar and tibial resections were performed as a standard technique [18,33]. The talar final component was inserted using the talar impactor to engage the pegs with the drilled holes and the final tibial component was inserted using the tibial impactor and a spacer to avoid contact between the two superfinished metal components. After meniscal bearing trials, the final meniscal bearing was inserted between the two metal components [18,33].

After surgery, a non-weight-bearing plaster cast was applied below the knee. After 2 weeks, the plaster cast was removed, and a weight-bearing walker boot was applied for 4 weeks. During this period, the patient started functional rehabilitation, including stretching exercises, water exercises and electrical muscle stimulation. Free weight-bearing was permitted 6 weeks after surgery.

2.7. Statistical Analysis

All continuous data were reported as means and standard deviations, while categorical variables were reported as percentages. When the variables had a normal distribution, a paired sample *t*-test was applied to compare pre- and postoperative parametric continuous variables. Statistical significance was defined as a *p*-value of less than 0.05 per standard deviation.

3. Results

3.1. Population

This study enrolled 8 patients (7 men and 1 woman) with 4 months of follow up. The mean age at the time of evaluation was 66.4 years. The average BMI was 28.14 kg/m^2. Six patients (75%) were operated on the right foot, while two (25%) were operated on the left foot (Table 2).

Table 2. Patients' characteristics.

Characteristics	No. (tot = 8)
Sex (M/F)	7/1
Age	66.4 ± 14.3 (48–81)
Side (Right/Left)	6/2
BMI	28.14 kg/m^2

Abbreviations: M: male; F: female; BMI: Body Mass Index.

3.2. Clinical Evaluation

The clinical outcomes measures through PROMs, which were administered to all patients, reported a significant improvement between the pre- and postoperative period in all cases, but one, with regard to the 17-IFFI score (Table 3).

Table 3. Clinical outcomes.

PROMs	Preop Score	Postop Score	*p*-Value
AOFAS	40.8 ± 15.3	63.2 ± 12.1	***0.005*** *
MOxFQ	66.9 ± 14.3	34.4 ± 14.9	***0.002*** *
VAS	4.9 ± 1.8	2.5 ± 2.1	***0.037*** *
SF-36	63.6 ± 9.4	74.2 ± 10.3	***0.027*** *
17-IFFI	50.6 ± 13.2	38.6 ± 21.4	*0.115*

* **Bold** *p*-value indicates reaching statistical significance.

No major complications were reported.

3.3. Physical Examination

No significant differences regarding the degrees or centimeters in the FPI and ALT between the pre- and postoperative period were recorded (Table 4).

Table 4. Physical examination outcomes.

	Preop Mean Value	Postop Mean Value	*p*-Value
FPI	1.9 ± 3.4	1.7 ± 2.4	*0.871*
ALT (°)	2.7 ± 7.6	3.6 ± 5.8	*0.626*
ALT (cm)	0.75 ± 2.1	1 ± 1.6	*0.626*

3.4. Baropodometric Platform

Differences from pre- to postoperative parameters are reported in Table 5.

Table 5. Baropodometric measurement outcomes.

		Preop Operated Foot	Postop Operated Foot	*p*-Value	Preop Non-Operated Foot	Postop Non-Operated Foot	*p*-Value
STATIC	Load distribution (%)	50.2 ± 6.1	49.9 ± 2.8	*0.889*	49.8 ± 6.1	50.2 ± 2.7	*0.889*
	Mean pressure (kPa)	35.8 ± 5.1	34.1 ± 3.2	*0.386*	33.1 ± 4.8	31.5 ± 4.5	*0.421*
	Peak pressure (kPa)	108.0 ± 28.9	115.0 ± 63.9	*0.770*			
	Foot barycenter (mm^2)	21.8 ±17.1	17.2 ± 13.9	*0.232*			
	Body barycenter (mm^2)	86.4 ± 78.6	42.3 ± 20.2	*0.191*			
	C.O.P. distance (mm)	169.9 ± 86.1	126.4 ± 30.9	*0.282*			
DYNAMIC	Mean pressure (kPa)	64.3 ± 7.2	68.9 ± 11.1	*0.301*	60.4 ± 6.1	70.6 ± 7.2	***0.036*** *
	Peak pressure in contact phase	145.3 ± 23.7	165.5 ± 29.1	*0.211*			
	Peak pressure in intermediate phase	143.5 ± 9.5	139.4 ± 30.2	*0.728*			
	Peak pressure in propulsion phase	181.9 ± 49.2	169.2 ± 59.7	*0.658*			

* **Bold** *p*-value indicates reaching statistical significance.

No significant differences were reported in the static measurements (Table 5), although a more uniform plantar pressure distribution was observed throughout the feet (Figure 4).

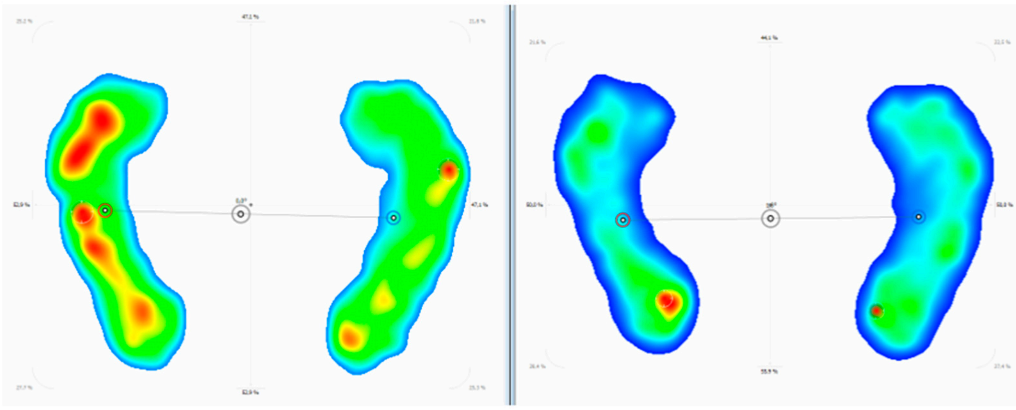

Figure 4. Visual plantar pressure distribution before (**left**) and after surgery (**right**). The software used a color code based on specific pressure levels, indicating the varying loads as strong (red), medium-strong (green) and medium (blue).

Preoperatively, peak pressure point was placed at the level of the calcaneus in 62.5% of cases, at the III metatarsal bone head in 25% of cases and at the II metatarsal head in 12.2% of cases. Postoperatively, peak pressure point was at the calcaneus in 87.5% and at the IV metatarsal base in 12.5%.

The dynamic examination showed no significant changes from the pre- to postoperative period, except for a significant increase in mean pressure for the non-operated foot (Table 5). The peak pressure during the contact phase was localized at the calcaneus in 87.5% of cases and at the V metatarsal base of the bone in 12.5% of cases before surgery; at the last follow up, the peak pressure was localized in 100% of cases at the calcaneus. Preoperatively, during the intermediate support phase, the peak pressure was localized at the calcaneus in 50%, 12.5% and 37.5% of cases at the I, III and V metatarsal heads, respectively. Postoperatively, the peak pressure was localized at the calcaneus in 75% of cases and at the V metatarsal base in 25% of cases. During the propulsion phase, the peak pressure was localized in 25% of cases, respectively, at the I, II, III and IV metatarsal head, and at the hallux in the remaining 12.5% of cases before surgery. On the other hand, after surgery, the peak pressure was localized in 25% of cases, respectively, at the I, II, III and V metatarsal head, at the hallux in 12.5% of cases, and at the calcaneus in the remaining 12.5% of cases.

3.5. Inertial Sensors

Differences from the pre- and postoperative foot parameters are reported in Table 6.

Table 6. Inertial sensors outcomes of the feet.

	Preop Both Feet	**Postop Both Feet**	***p*-Value**	**Preop Operated Foot**	**Postop Operated Foot**	***p*-Value**	**Preop Non-Operated Foot**	**Postop Non-Operated Foot**	***p*-Value**
Walking speed (m/min)	56.6 ± 10.8	52.3 ± 13.3	*0.114*						
Cadence (steps/min)	45.3 ± 4.6	47.7 ± 11.2	*0.544*						
Stride length (m)	1.25 ± 0.1	1.10 ± 0.1	***0.031*** *						
Stride duration (s)	1.33 ± 0.1	1.32 ± 0.3	*0.911*						
Step length (m)				0.63 ± 0.1	0.54 ± 0.1	***0.003*** *	0.61 ± 0.1	0.56 ± 0.1	*0.206*
Step duration (s)				0.65 ± 0.1	0.61 ± 0.2	*0.581*	0.68 ± 0.1	0.71 ± 0.2	*0.635*
Stance duration (%)				60.8 ± 1.9	62.0 ± 5.4	*0.564*	62.3 ± 2.6	65.8 ± 6.7	*0.195*
Swing duration (%)				37.0 ± 2.1	36.5 ± 4.9	*0.812*	35.9 ± 2.6	32.4 ± 6.5	*0.189*
Double support duration (%)	12.6 ± 1.1	14.5 ± 2.6	*0.089*						
Gait variability (%)				4.9 ± 0.9	6.4 ± 4.7	*0.423*	5.9 ± 2.2	6.6 ± 2.9	*0.499*
Symmetry index	0.9 ± 0.1	1.1 ± 0.3	*0.265*						

* **Bold** *p*-value indicates reaching statistical significance.

No significant differences were reported for most of the parameters between the pre- and postoperative period, and only the stride length decreased significantly after surgery, as well the step length regarding the operated feet.

Regarding pelvic movement during gait (Table 7), no significant changes were recorded.

Table 7. Inertial sensors outcomes of pelvic movement.

	Preop	**Postop**	***p*-Value**
Tilt (°)	0.87 ± 0.8	0.35 ± 0.3	*0.139*
Obliquity (°)	0.17 ± 0.1	0.61 ± 0.9	*0.198*
Rotation (°)	0.28 ± 0.2	0.48 ± 0.4	*0.283*

Inertial sensors measurement of the ankle's ROM (Table 8) showed a significant decrease in the active and passive plantar flexion between the pre- and postoperative period.

Table 8. Inertial sensors outcomes of ankles.

	Preop Operated Foot Mean Value	**Postop Operated Foot Mean Value**	***p*-Value**
Active dorsal flexion (°)	14.4 ± 7.9	11.6 ± 4.9	*0.417*
Passive dorsal flexion (°)	13.8 ± 9.2	14.3 ± 5.6	*0.898*
Active plantar flexion (°)	21.4 ± 6.2	11.6 ± 4.8	***0.014*** *
Passive plantar flexion (°)	21.5 ± 8.4	16.5 ± 4.2	***0.044*** *

* **Bold** *p*-value indicates reaching statistical significance.

4. Discussion

A feasibility study was performed in order to demonstrate the benefits of wearable monitoring during postoperative TAA recovery, and, to our knowledge, this research may be considered the first study that applied wearable inertial sensors to investigate the ankle's joint motions and kinematic outcomes after TAA surgery.

In detail, this study reported early results of a consecutive series of patients with end-stage ankle OA before and after TAA surgery, using PROMs and an innovative assessment of used for ankle joint angles, plantar pressures and kinematic variables.

TAA was proposed in order to preserve joint motion [16] and allow for a more physiological gait pattern. Innovative tools such as the baropodometric platform and inertial sensors can be used to assess the outcomes and reliability of surgical procedures [34–37].

With regard to the PROMs, all but one showed a statistically significant improvement; however, PROM values were still low compared to those reported in the literature, potentially due to an early follow up, which in line with the literature [6,38–42]. The physical examination showed no significant changes of the foot shape and alignment; however, the only study using these specific tests after TAA reported significant improvements with a longer follow up [7].

TAA surgery relieved pain and hypothetically helped to improve plantar support and gait [8,38–43]. Plantar pressure analysis with the baropodometric platform showed no significant changes in the evaluation of a static position. However, a more uniform plantar pressure distribution was observed throughout the feet, even if it was not statistically significance. In the dynamic evaluation, however, a significant increase in the mean pressure of the non-operated foot was recorded between the pre- and postoperative period, probably due to a compensatory mechanism acting to unload the operated foot. Indeed, the literature reported that the patient achieves a more balanced gait in relation to the gradual progress of rehabilitation [41,44]. Although no significant changes between the pre- and postoperative period were reported, the dynamic evaluation after surgery showed a satisfied peak pressure distribution throughout the feet for many patients, which correlated with the findings reported in the literature, i.e., peak pressure is localized at the level of the calcaneus during the contact phase and at the level of the head of the I metatarsal bone during the intermediate and propulsive support phases [9,11,41,45].

The inertial sensor parameters that improved early were those that are not fully affected by rehabilitation, such as stride and step length [8,38–40,42,43]. Some studies showed that the gait pattern improved 12 months postoperatively, after the physical rehabilitation program's conclusion [8,41,42]. Generally, the outcomes became worse at a 3-month follow up, and then gradually improved significantly with a longer follow up, as shown in various studies [8,38–40,42,43]. In our study, a few parameters of the patients showed significant changes between the pre- and postoperative period, which may be due to the very short-term follow-up period used. This was also the case regarding ankle inertial sensors measurements, which reported a significant reduction in both active and passive plantar flexion after surgery.

Another crucial aspect to consider is the cost effectiveness of these tools. To accurately define this aspect, the cost of each evaluation should also be assessed. However, wearable sensor motion analysis and activity monitoring have been extensively utilized in numerous clinical settings thanks to their low cost and ease of application, even by non-experts. This approach often requires a similar or shorter time than administering a questionnaire, complements conventional clinical scores and provides additional diagnostic values or evidence of outcomes [46].

Patients undergoing elective ankle surgery may benefit from wearable devices that monitor their walking gait and mobility metrics; however, the degree of benefit of TAA surgery on a person's kinematics, plantar pressure and ankle joint motion require further investigation with studies employing a different design (RCT) and a larger sample. Further studies should also evaluate the effects of TAA surgery at one year postoperatively in order to better understand the analysis from wearable devices over time and the long-term clinical impacts of surgery.

Limitations and Future Direction

This study is not without limitations: First, the number of patients and the short-term follow up are among its limitations. However, pilot studies are important in order to avoid significant errors before implementing large-scale studies, to assess the feasibility of particular aspects of their proposed studies and to obtain preliminary data that can be used to design a relevant, economical and statistically adequate large-scale study. Evaluations of intra-rater and inter-rater reliability of inertial sensors' analyses are still needed. Moreover, the results were difficult to compare in the literature due to the lack of studies that assess the effectiveness of TAA surgery using inertial sensors.

5. Conclusions

After TAA, results are commonly based on clinical or radiographical findings. Wearable-based joint ankle analysis might be part of the clinical assessment used to better understand the efficacy of the surgical procedure that was utilized. Gait analysis employing inertial sensors after TAA yielded encouraging findings. Although satisfactory clinical outcomes were reported, minimal alterations in plantar pressures and kinematic variables were observed, which were likely attributable to the brief duration of the follow-up period. These innovative tools are easy to handle, cost-effective, portability, do not require a dedicated laboratory, and present ease and speed in reading data. Their notable advantages make them particularly attractive for widespread clinical use. As we look to the future, incorporating these tools into routine assessments for patients with TAA can enhance the precision and depth of our understanding, ultimately contributing to more comprehensive and insightful patient care.

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Data Availability Statement: The data presented in this study are available on request from the corresponding author; however, restrictions apply to the availability of these data, which were used under license for this study, and they are thus not publicly available.

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List of Abbreviations

17-IFFI	17-Italian Foot Function Index
AA	Ankle arthrodesis
ALT	Ankle Lunge Test
AOFAS-AHES	American Orthopaedic Foot and Ankle Society Ankle-Hindfoot Score
BMI	Body Mass Index
C.O.P.	Barycenter and center of pressure
FPI	Foot Posture Index
IMUs	Inertial measurement units

MOxFQ	Manchester–Oxford Foot Questionnaire
OA	Osteoarthritis
PROM	Patient-related outcome measure
ROM	Range of motion
SF-36	Short-Form Health Survey
TAA	Total ankle arthroplasty
VAS	Visual Analogue Scale

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