



Article RObotic-Assisted Rehabilitation of Lower Limbs for Orthopedic Patients (ROAR-O): A Randomized Controlled Trial

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Abstract: Osteoarthritis is a common chronic condition in the elderly population and, with falls, represents a major public health problem. Patients with hip or knee osteoarthritis often have poor balance, which is considered an important risk factor for falls. In recent years, there has been increasing research supporting the use of robotic rehabilitation to improve function after total knee and hip replacement. The aim of this study is to investigate the effects of robotic balance rehabilitation on elderly patients who have undergone hip and knee replacement, with the aim of reducing the risk of falls and improving balance and walking, as well as motor function, fatigue, and overall quality of life. Twenty-four elderly patients with knee or hip replacement underwent robotic balance treatment with the Hunova[®] platform or conventional treatment three times a week for four weeks. Patients underwent an assessment of balance, walking, autonomy, quality of life and fatigue. Patients who underwent rehabilitation with Hunova[®] showed an improvement in dynamic balance (*p* = 0.0039) and walking (*p* = 0.001) and a reduction in both motor (*p* = 0.001) and cognitive (*p* = 0.05) fatigue. The study found that specific treatment for balance disorders in these patients could improve balance and reduce the risk of falling.

Keywords: technological rehabilitation; balance; osteoarthritis; elderly

1. Introduction

Osteoarthritis, often known as OA, is a chronic condition characterised by a degenerative process that causes the joint to lose more and more structural components. It causes the gradual wear and tear of the articular cartilage, which are the tissues that lines the ends of bones, which in turn causes reactive neoformation of bone tissue, resulting in joint restriction and discomfort [1]. Several studies have shown that more than thirty percent of adults over the age of sixty-five, i.e., approximately one in three, experience a fall on a yearly basis [2–4]. The risk of falling may even increase by more than 50 percent with increasing age or in the presence of specific pathologies associated with ageing; in fact, OA affects almost all people in their 70 s, with the incidence reaching its highest point between the ages of 75 and 79 [2,3].

Falls are a common cause of illness and mortality, and often compromise people's level of independence, which can lead to an early need for assistance. In 2022, it was estimated that 28.6 per cent of people over 65 years in Italy fall during a year; of these, 43 per cent fall more than once, and 60 per cent of falls occur at home [4,5]. Falls and osteoarthritis are both major issues that affect public health. Falls are the second leading



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Copyright: © 2023 by the authors. Licensee MDPI, Basel, Switzerland. This article is an open access article distributed under the terms and conditions of the Creative Commons Attribution (CC BY) license (https:// creativecommons.org/licenses/by/ 4.0/). cause of death from unintentional injuries worldwide, and an estimated 37.3 million people require medical care each year because of their injuries [6]. Fractures are a major cause of death and morbidity, as well as a strain on the socioeconomic system [7,8]. The elderly have an increased risk of suffering from hip and knee osteoarthritis [9], as well as hip and knee fractures [10].

Patients suffering from knee and hip OA often experience pain, muscle weakness, impaired joint proprioception, and poor balance, all of which are important risk factors for falls [11–13]. There is a correlation between fall risk and measurements in several domains, such as assessment of cognitive and physical functioning, gender, age, comorbidities, medication use, fear of falling, and environmental factors [14]. Age and gender are two aspects of a person's life that cannot be changed, and are among the elements that contribute to the likelihood of falling.

Muscle function, balance control, and gait quality are three of the most significant determinants of fall risk; however, effective fall prevention interventions can improve these factors [15,16]. Fractures, requiring hospitalisation, are a common consequence of falls, which also have an important negative effect on both motor and cognitive function. In particular, for elderly patients undergoing hip or knee replacement surgery, the rehabilitation procedure for recovering the sense of balance and ability to walk is of paramount importance for improving person's autonomy and independence. In addition, to have a good recovery after hip or knee replacement surgery, it is essential to engage in rehabilitation activities that improve walking ability and sense of balance while reducing the risk of falling. In the past, post-surgical therapies for knee replacement have emphasized 'conventional' treatment protocols. These protocols included activities to improve range of motion, stretching, and development of strength and endurance. Nevertheless, this rehabilitation strategy did not significantly improve either the patient's level of discomfort or limb function [17]. On the other hand, more recent research has included more targeted balance therapies, both bipodal and monopodal, with an emphasis on the fact that a better outcome was achieved by introducing rehabilitative activities that stress the sensory systems involved in balance [18].

The most effective form of exercise-based therapy is one that combines strength training with other types of exercise, particularly functional and balance activities. For an exercise routine to be effective in reducing an individual's number of stumbles and falls, it must be condensed in terms of both duration and intensity [19]. In addition, the use of perturbation-based therapies [20] and stepping interventions helps to prevent the occurrence of falls [21].

A higher level of intensity, objectivity, and standardisation of treatment procedures, as well as the measurement of results, are possible with technological and robotic rehabilitation [22–24]. In recent years, research supporting the use of robotic rehabilitation to improve function after total knee and hip replacement has increased [25–28]. In particular, the use of exoskeletal robots and end-effectors for gait recovery is gaining popularity [29,30].

Considering the literature on the topic [31–33], the purpose of the study is to investigate the effects of robotic balance rehabilitation on elderly patients who have undergone hip and knee replacements, with the aim of reducing the risk of falls and improving balance and walking, as well as motor function, fatigue, and overall quality of life.

2. Materials and Methods

This is an interventional, randomised, controlled pilot study. Patients from the Post-Acute Rehabilitation Unit of the Fondazione Policlinico Universitario A. Gemelli IRCCS in Rome were evaluated between September 2022 and June 2023.

2.1. Inclusion and Exclusion Criteria

Patients had to meet the following inclusion requirements to be included in the study: (i) ages \geq 55; (ii) results of total or partial prosthetic hip or knee replacement surgery; (iii) latency from the acute event between 5 days and 3 months; (iv) cognitive ability such that they could follow simple instructions and understand physiotherapist instructions, as measured by the Token Test (score \geq 26.5); (v) ability to walk without assistance or with minimal help; and (vi) understanding and signing of informed consent.

In contrast, patients with: (i) systemic, neurological, cardiac pathologies that made walking dangerous or caused motor deficits; (ii) oncological conditions; (iii) plantar ulcers; or (iv) partial or total amputation of foot segments were excluded.

Patients who met the participation requirements were randomly assigned to one of two groups: the experimental group, referred to as G-Hun, or the conventional group, referred to as G-Conv. In addition to the traditional treatment that was offered by the clinical practice, G-Hun patients participated in a specialised rehabilitation treatment for balance using the Hunova[®] robotic platform (Movendo Technology srl, Genoa, Italy). In contrast, G-Conv patients were only required to receive traditional treatment on a daily basis.

2.2. Clinical and Technological Assessment

At baseline (T0) and after 4 weeks of treatment (T1), all patients underwent clinical and instrumental assessment.

Clinical evaluation was performed using scales assessing motor performance and balance, walking, autonomy, quality of life and fatigue.

The Berg Balance Scale (BBS), the Time Up&Go (TUG), the Italian Knee Injury and Osteoarthritis Outcome Score (KOOS-I) and the Italian Hip disability and Osteoarthritis Outcome Score (HOOS-I), the Short Physical Performance Battery (SPPB) and the Motricity Index-Lower Limb (MI-LL) were used to assess motor performance and balance.

The BBS is an instrument used to assess a patient's ability or inability to maintain balance during a series of tasks, both static and dynamic. It is a scale consisting of 14 tasks, for each of which a value ranging from 0 to 4 can be assigned, where 0 indicates the inability to perform or complete the proposed task and 4 the highest level of functionality. A score below 45 indicates an increased risk of falling [34]. The TUG is a test to assess the risk of falling in the elderly. It is performed by recording the speed with which a patient is able to get up from a chair, walk a distance of 3 metres, turn around, return to the chair and sit down. In the elderly population, a time ≥ 12 indicates a risk of falling [35]. The HOOS and KOOS are two extremely similar self-administered questionnaires investigating symptoms, at the hip joint level in the former, and at the knee level in the latter. They consist of 40 and 42 items, respectively; both are divided into five subscales (symptoms, pain, activities of daily living, physical function, sports and recreational activities, and quality of life). All items can be scored from 0 (no difficulty) to 4 (high difficulty). For each subscale, the result is calculated as a percentage, where higher percentages correspond to a better condition [36,37]. The SPPB is a test that assesses balance, lower limb strength and functional capacity in the elderly. Three specific domains are assessed, i.e., the ability to stand for 10 s with feet in three different positions (side-by-side, semi-tandem and tandem); gait, which is assessed by recording the time taken by the patient to walk 3 or 4 metres (the fastest recorded); and the time taken by the patient to get up from a chair five times [38,39]. The MI-LL is a test used to assess motor impairment. Ankle dorsiflexion, knee extension, and hip flexion are assessed for each lower limb [40].

The walking assessment was carried out through the Ambulation Index (AI), the Walking Handicap Scale (WHS), the Functional Ambulation Classification (FAC), the 10-Meter Walking Test (10 MWT), and the 6-Minute Walking Test (6 MWT).

The AI is a mobility assessment scale that evaluates the time and degree of assistance needed to walk 8 metres. The patient is asked to walk 8 metres as quickly and safely as possible, while the travel time and the type of assistance needed are recorded. The travel time is used to assign a score to the patient: lower scores correspond to a higher degree of independence and activity [41]. The WHS is a scale used to assess the quality of walking in the home and social environment through six categories. Category 1 corresponds to 'walking only for exercise', while category 6 corresponds to 'walking in the social

environment without limitations' [42]. The FAC is a functional gait test that assesses the patient's ability to walk and the amount of help needed. A higher score corresponds to the ability to walk independently [43]. The 10 mWT is a performance test that is used to assess how long it takes a patient to travel a predetermined distance [44]. The 6 MWT is a test that assesses walking endurance. The patient is asked to walk as far as possible in six minutes. The final score is given by the metres walked by the patient [45].

For the assessment of autonomy, quality of life, and fatigue, the modified Barthel Index (mBI), the EuroQoL-5D (EQ-5D) and the Modified Fatigue Impact Scale (MFIS) were used.

The mBI is a scale that measures autonomy in performing the activities of daily living (ADLs), such as personal hygiene, the ability to wash oneself, feed oneself, use the toilet, the ability to dress oneself, bladder and bowel control, the ability to make transfers, the use of a wheelchair, and the ability to walk and climb stairs. Higher scores correspond to greater autonomy in ADLs [46]. The EQ-5D is an instrument used to assess health-related quality of life. Overall, it assesses five dimensions: mobility, self-care, habitual activities, pain, and anxiety/depression. Higher scores correspond to a worse health status [47]. The MFIS is a scale that evaluates the influence that fatigue has on people's lives. The impact of weariness on a person's physical, cognitive, and psychosocial functioning can be evaluated with the help of this test. It consists of 21 items, each of which is assessed using a Likert scale with five points, ranging from 0 (meaning "never") to 4 (meaning "almost always"). In addition to the overall score, it is possible to extract scores for the physical subscale, the cognitive subscale, and the psychosocial subscale. Scores higher than 10 indicate increased levels of weariness [48,49].

Considering instrumental assessment, the balance assessment was performed with the use of the robotic platform (Hunova[®] Movendo Technology srl, Genoa, Italy). In particular, the balance assessment was performed in both static and dynamic conditions while the subject was standing. Specifically, stabilometric data were collected from the analysis of centre of pressure (CoP) trajectories. Subsequently, the following balance performance factors were calculated from the instantaneous CoP positions: CoP oscillation velocity along the antero-posterior (AP) and mid-lateral (ML) axis, CoP trajectory length, area of the 95% confidence ellipse, and the Romberg Test [ratio of the length value in the eyes closed (OC) condition to the same value in the eyes open (OA) condition]. In addition, trunk movement data were also collected.

2.3. Procedures

The Hunova[®] robotic platform is a medical device consisting of two electromechanical platforms, a foot platform and the seat platform [50].

G-Hun patients underwent robotic treatment for improving balance using Hunova[®] 3 times a week for 45 min each, in addition to conventional treatment. In particular, the technological rehabilitation performed with Hunova[®] mainly aimed to improve balance, both sitting and standing; static and dynamic exercises, dual-task exercises and exercises to improve trunk control were proposed. In particular, technological rehabilitation was mainly geared towards improving balance, both in a sitting and standing position.

As for the standing exercises, they were first performed in bipodal position. This position was adopted to train the patient to handle the load appropriately, to maintain the standing position both in quiet environments and during activities that require continuous adjustment of standing and trunk control, and to keep the load in the correct position. Subsequently, training was performed to strengthen the core and improve proprioception, both on a stationary platform and using different perturbation modes (elastic mode, fluid mode). As treatment progressed, exercises were performed in monopodal support, both on the operated limb and the healthy limb, to restore proper load management and proprioception, as well as to strengthen muscle tissue.

To strengthen the trunk and improve load control on the lower limbs and pelvis, exercises performed while seated focused on these areas.

To train the patient to complete several tasks simultaneously, dual-task activities were performed while sitting and standing. Cognitive–motor coordination and dual-task activities were performed.

G-Conv patients underwent only conventional rehabilitation treatment using major rehabilitation methods (e.g., neurocognitive theory, progressive neuromuscular facilitation, etc.).

2.4. Statistical Analysis

As this is a pilot study on a specific subgroup of patients, on whom the actual usefulness of the Hunova[®] has not yet been studied in the literature, the study was set up as a pilot study. As such, no formal sample sizing was necessary. However, based on Julious' rules (2005) of thumb for clinical pilot studies [51], 12 subjects per group were included for a total population of 24 subjects.

The division into the two groups followed a randomisation algorithm according to the random sorting procedure. The allocation sequence was generated through PASS2019 software.

The sample was described in its clinical and demographic variables using descriptive statistical techniques. Quantitative variables were summarized with mean and standard deviation (SD), and median and interquartile range (IQR) where appropriate. Qualitative variables were presented through absolute and percentage frequency tables.

The Shapiro–Wilk probability test was used to assess the normality of the distributions [52]. The within-group analysis was based on the application of the Wilcoxon Signed Rank test for each clinical and instrumental balance outcome registered at T0 and T1.

The between-group analysis was performed using The Mann–Whitney U test to compare the percentage increase calculated for each group.

Regarding the clinical outcome, the between-group differences were analyzed by comparing the changes from baseline of each clinical scale, defined as S(T1) - S(T0), where S is one of the clinical outcomes. Instead, regarding the instrumental outcome, the between-group differences were analyzed by comparing the percentage increase in each outcome, defined as $\Delta S = \frac{(S(T1) - S(T0))}{(S(T0))}$.

The between-group analysis of clinical scales were conducted by considering the differences between the scores, S(T1) - S(T0), because the minimum value of almost all scales is 0, and normalization was not thus possible.

Statistical significance for each test was set at 0.05. Statistical analysis was performed with SPSS 25 (IBM Corp., Armonk, NY, USA).

3. Results

Some 24 patients admitted to the post-acute rehabilitation unit between September 2022 and June 2023, 10 men and 14 women, with a mean age of 67.64 years (standard deviation of ± 23.67 years), were included in the study. The two groups did not differ in terms of clinical and demographic characteristics, as shown in Table 1.

Table 1. Clinical and demographical characteristic of the whole sample at baseline.

		G-Hun (<i>n</i> = 12)	G-Conv (<i>n</i> = 12)	<i>p</i> Value
Gender, %	Male vs. Female	33.33 % vs. 66.67 %	50.00 % vs. 50.00 %	p = 0.410
Age, years	$\text{Mean}\pm\text{SD}$	69.1 ± 24.6	65.6 ± 24.3	p = 0.887
Latency, days	$\text{Mean}\pm\text{SD}$	5.0 ± 1.4	5.0 ± 1.6	p = 0.514
Type of prosthesis, %	Knee vs. Hip	58.33 % vs. 41.67 %	41.67 % vs. 58.33 %	p = 1.000
Affected size, %	Left vs. Right	66.67 % vs. 33.33 %	58.33 % vs. 41.67 %	p = 0.755

G-Hun: experimental group G-Conv: conventional group; SD: standard deviation.

Considering the motor, balance and walking assessments, the intragroup analysis showed statistically significant improvements in the clinical scales in both groups, as shown in Table 2. Regarding the intergroup comparison of clinical scales, however, a statistically significant difference was found in TUG (p = 0.039), 10 MWT (p = 0.001) and 6 MWT (p = 0.001) values (Figure 1).

Table 2. Intra-group and inter-group analysis of motor function, balance, gait and fatigue, autonomy and quality-of-life scales.

		G-Hun			G-Con				
	T0 Median (IQR)	T1 Median (IQR)	p Value	T0 Median (IQR)	T1 Median (IQR)	p Value	<i>p</i> Value G-Hun vs. G-Con		
Motor function, balance and gait									
MI-LL prosthetic side	61.5 (48.75–65.5)	77 (74.5–92)	p = 0.002	64 (52.5–66)	87 (74.5–91.25)	p = 0.013	p = 0.319		
MI-LL non-prosthetic side	88 (82–100)	100 (92–100)	<i>p</i> = 0.016	88 (76–94)	95.5 (91–100)	p = 0.017	<i>p</i> = 0.799		
TUG	31.60 (27.63–63.5)	22.93 (19.14–26.86)	p = 0.002	23.85 (17.32–27.62)	12.82 (8.3–24.29)	p = 0.002	p = 0.039		
BBS	30 (22.75–32.25)	42 (38.75–48.5)	p = 0.02	28 (18–33)	38.5 (33–54)	p = 0.003	p = 0.089		
SPPB_B	1 (1–2)	2 (2–3)	p = 0.002	1 (1–1)	2 (1.75–4)	p = 0.007	p = 0.713		
SPPB_W	1 (1–1)	2 (1–2)	p = 0.007	1 (1–1)	1 (1–3)	<i>p</i> = 0.039	p = 0.843		
SPPB_STS	1 (1–1)	2 (1.75–2)	p = 0.004	1 (1–1)	1 (1-4)	p = 0.007	p = 0.843		
SPPB_TOT	3 (2.75–4)	6 (5–6)	<i>p</i> = 0.002	3 (3–3)	4 (3.75–11)	p = 0.011	p = 0.514		
HAI	5 (4.75–6)	3 (2.75–4)	p = 0.002	4.5 (2–5.25)	2 (2–2.5)	p = 0.053	p = 0.671		
FAC	1.5 (1–2)	4 (3–4)	p = 0.002	2 (2–3)	3 (2.75–5)	p = 0.002	p = 0.219		
WHS	2 (2–1)	3.5 (3–4)	p = 0.001	2 (2–2)	3 (3–5)	p = 0.002	p = 0.932		
10 MWT	20.16 (16.86-28.61)	12.19 (11.29–18.58)	p = 0.001	17.4 (14.8–18.24)	15.69 (13.79–16.38)	p = 0.002	p = 0.001		
6 MWT	77.5 (60–106.25)	175 (133.75–212.5)	p = 0.002	100 (85–1656)	150 (143.75–190)	p = 0.003	p = 0.001		
Fatigue, autonomy, a							0.010		
mBI	50.5 (42.75–58.5)	91 (84–92.75)	<i>p</i> = 0.002	43 (37.75–43)	64 (56–87)	<i>p</i> = 0.002	<i>p</i> = 0.219		
EQ-5D_VAS	52.5 (43.75-60)	85 (80-86.25)	p = 0.003	47.5 (45-53.75)	80 (70-85)	p = 0.003	p = 0.630		
EQ-5D TOT	11 (10.5–15.25)	7 (6–7.25)	p = 0.002	15 (14–15)	9 (7–11)	p = 0.002	p = 0.713		
MFIS_PHY	25 (22.5–28.25)	14 (10–16.5)	p = 0.002	22 (21–22.25)	19 (16–19)	p = 0.002	p = 0.001		
MFIS_COG	13 (12–18.25)	3 (2–3.25)	<i>p</i> = 0.003	11 (9–16.75)	8 (6–12)	p = 0.002	p = 0.05		
MFIS_PSY	7 (5.5–7.25)	3 (2–3.25)	<i>p</i> = 0.003	5 (4.75–6.25)	3 (2–3)	<i>p</i> = 0.003	p = 0.514		
MFIS_TOT	43.5 (42–50.75)	23.5 (17.75–29.25)	p = 0.002	41 (36–44)	30 (28–30)	p = 0.002	p = 0.002		

G-Hun: experimental group G-Conv: conventional group; MI-LL: Motricity index-Lower Limb; TUG: Timed Up&Go; BBS: Berg Balance Scale; SPPB_B: Short Physical Performance Battery_Balance; SPPB_W: Short Physical Performance Battery_Sit To Stand; HAI: Hauser Ambulation index; FAC: Functional Ambulation Classification; WHS: Walking Handicap Scale; 10 MWT: 10-Meter Walking Test; 6 MWT: 6-Minute Walking Test; mBI: modified Barthel Index; EQ-5D: EuroQuoL-5 Dimensions; MFIS_PHY: Modified Fatigue impact Scale_Physical; MFIS_COG: Modified Fatigue impact Scale_Cognitive; MFIS_PSY: Modified Fatigue impact Scale_Psycosocial; in bold the significant results for p < 0.05.

Regarding the ratings of fatigue, autonomy and quality of life, the intra-group analysis showed significant improvements for all the rating scales used, for both G-Hun and G-Conv. Comparing the two groups, a statistically significant difference was found in MFIS (p = 0.002), particularly for the physical subscale (p = 0.001) and the cognitive subscale (p = 0.05).

Considering the subgroup of patients who underwent knee replacement, the intragroup analysis between those who underwent robotic balance rehabilitation and those who underwent conventional rehabilitation showed statistically significant differences in most of the subscales comprising the KOOS-I, with the exception of the subscale related to activities of daily living in the G-Hun (p = 0.080) and the G-Conv (p = 0.170) groups.

Otherwise, considering the subgroup of patients undergoing hip replacement, intragroup analysis showed statistically significant results in all subscales of the HOOS-I only in the G-Hun group (Table 3).

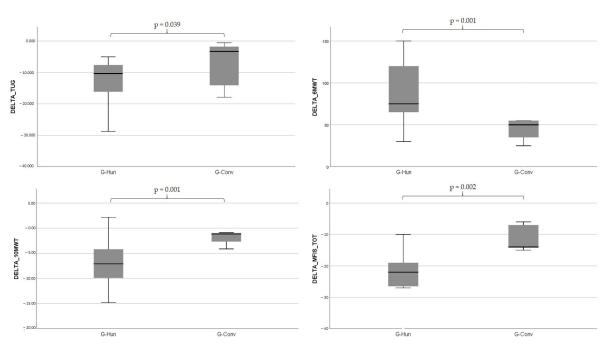


Figure 1. Comparison of dynamic balance, walking, and fatigue between G-Hun and G-Conv.

Table 3. Intra-group analysis of Italian version of Knee Injury and Osteoarthritis Outcome score and the Italian version of Hip Injury and Osteoarthritis Outcome score for both groups.

G-Hun			G-Conv			
T0 Median (IQR)	T1 Median (IQR)	p Value	T0 Median (IQR)	T1 Median (IQR)	p Value	
70 (65–75)	35 (25–45)	<i>p</i> = 0.013	91.66 (91.66–100)	75 (75–75)	p = 0.046	
69.45 (66.66–75)	41.67 (41.67–52.77)	p = 0.043	80 (80–100)	33.34 (33.34 + 75)	p = 0.046	
69.12 (67.64–79.42)	48.53 (45.49–52.95)	p = 0.080	70.58 (70.58–92.65)	51.18 (30.89–72.05)	p=0.170	
100 (100–100)	50 (52–75)	p = 0.024	100 (100–100)	81.25 (45-81.25)	p = 0.042	
75 (62.5–81.25)	27.5 (25–31.25)	p = 0.033	75 (68.75–75)	62.25 (56.25-62.25)	p = 0.036	
74.50 (74.18–78.21)	42.02 (31.45-45.10)	p = 0.013	82.04 (82.04–93.57)	58.43 (45.25–70.34)	p = 0.016	
66.67 (63.33–79.17)	33.33 (25–45.83)	<i>p</i> = 0.018	75 (75–75)	66.67 (66.67-84.3)	p = 0.680	
69.95 (62.5-83.75)	52 (32.5–37.5)	p = 0.018	57.5 (57.5–57.5)	52 (32.5–80)	p = 0.892	
70.59 (60.88–75.74)	43.75 (31.61–52.8)	p = 0.018	60.3 (60.3–60.3)	54.42 (51.18-64.71)	p = 0.684	
100 (100–100)	50 (46.88-62.5)	p = 0.017	100 (43.75-81.2)	100 (100–100)	p = 0.180	
68.42 (65.25–75)	18.75 (11.13–31.25)	p = 0.018	52 (43.75–81.2)	62.75 (62.75–62.75)	p = 0.684	
78.32 (70.70-80.09)	36.89 (31.93–47.63)	<i>p</i> = 0.018	67.47 (54.70–70.67)	60.10 (58.43–72.60)	p = 0.684	
	Median (IQR) 70 (65–75) 69.45 (66.66–75) 69.12 (67.64–79.42) 100 (100–100) 75 (62.5–81.25) 74.50 (74.18–78.21) 66.67 (63.33–79.17) 69.95 (62.5–83.75) 70.59 (60.88–75.74) 100 (100–100) 68.42 (65.25–75)	T0 T1 Median (IQR) 70 (65-75) 35 (25-45) 69.45 (66.66-75) 41.67 (41.67-52.77) 69.12 (67.64-79.42) 48.53 (45.49-52.95) 100 (100-100) 50 (52-75) 75 (62.5-81.25) 27.5 (25-31.25) 74.50 (74.18-78.21) 42.02 (31.45-45.10) 66.67 (63.33-79.17) 33.33 (25-45.83) 69.95 (62.5-83.75) 52 (32.5-37.5) 70.59 (60.88-75.74) 43.75 (31.61-52.8) 100 (100-100) 50 (46.88-62.5) 68.42 (65.25-75) 18.75 (11.13-31.25)	T0T1 p ValueMedian (IQR)Median (IQR) p Value70 (65-75) $35 (25-45)$ $p = 0.013$ 69.45 (66.66-75) $41.67 (41.67-52.77)$ $p = 0.043$ 69.12 (67.64-79.42) $48.53 (45.49-52.95)$ $p = 0.080$ 100 (100-100) $50 (52-75)$ $p = 0.024$ 75 (62.5-81.25) $27.5 (25-31.25)$ $p = 0.033$ 74.50 (74.18-78.21) $42.02 (31.45-45.10)$ $p = 0.013$ 66.67 (63.33-79.17) $33.33 (25-45.83)$ $p = 0.018$ 69.95 (62.5-83.75) $52 (32.5-37.5)$ $p = 0.018$ 70.59 (60.88-75.74) $43.75 (31.61-52.8)$ $p = 0.017$ 68.42 (65.25-75)18.75 (11.13-31.25) $p = 0.018$	T0T1 p ValueT0Median (IQR) p ValueT070 (65-75) $35 (25-45)$ $p = 0.013$ 91.66 (91.66-100)69.45 (66.66-75) $41.67 (41.67-52.77)$ $p = 0.043$ 80 (80-100)69.12 (67.64-79.42) $48.53 (45.49-52.95)$ $p = 0.080$ 70 (100-100)50 (52-75) $p = 0.024$ 100 (100-100)50 (52-75) $p = 0.033$ 75 (62.5-81.25)27.5 (25-31.25) $p = 0.013$ 82.04 (82.04-93.57)66.67 (63.33-79.17) $33.33 (25-45.83)$ $p = 0.018$ 75 (75-75)69.95 (62.5-83.75)52 (32.5-37.5) $p = 0.018$ 70.59 (60.88-75.74) $43.75 (31.61-52.8)$ $p = 0.018$ 66.42 (65.25-75)18.75 (11.13-31.25) $p = 0.018$ 52 (43.75-81.2)52 (43.75-81.2)	T0T1 p ValueT0T1Median (IQR)Median (IQR)70 (65-75)35 (25-45) $p = 0.013$ 91.66 (91.66-100)75 (75-75)69.45 (66.66-75)41.67 (41.67-52.77) $p = 0.043$ 80 (80-100)33.34 (33.34 + 75)69.12 (67.64-79.42)48.53 (45.49-52.95) $p = 0.080$ 70.58 (70.58-92.65)51.18 (30.89-72.05)100 (100-100)50 (52-75) $p = 0.024$ 100 (100-100)81.25 (45-81.25)75 (62.5-81.25)27.5 (25-31.25) $p = 0.033$ 75 (68.75-75)62.25 (56.25-62.25)74.50 (74.18-78.21)42.02 (31.45-45.10) $p = 0.013$ 82.04 (82.04-93.57)58.43 (45.25-70.34)66.67 (63.33-79.17)33.33 (25-45.83) $p = 0.018$ 75 (75-75)66.67 (66.67-84.3)69.95 (62.5-83.75)52 (32.5-37.5) $p = 0.018$ 57.5 (57.5-57.5)52 (32.5-80)70.59 (60.88-75.74)43.75 (31.61-52.8) $p = 0.017$ 100 (43.75-81.2)100 (100-100)68.42 (65.25-75)18.75 (11.13-31.25) $p = 0.018$ 52 (43.75-81.2)62.75 (62.75-62.75)	

G-Hun: experimental group G-Conv: conventional group; KOOS_S: KOOS_Symptoms; KOOS_P: KOOS_Pain; KOOS_ADL: KOOS_ACtivity of Daily Living; KOOS_QoL: KOOS_Quality of Life; HOOS_S: HOOS_Symptoms; HOOS_P: HOOS_Pain; HOOS_ADL: HOOS_Activity of Daily Living; HOOS_QoL: HOOS_Quality of Life; significant results at p < 0.05 are in bold.

On the other hand, regarding the instrumental assessment of static balance, the intragroup analysis showed no statistically significant results for either G-Hun or G-Conv. In contrast, the intergroup comparison showed statistically significant results for the Romberg index (p = 0.047) and the COP sway range in the mid-lateral direction with open eyes (p = 0.026).

Conversely, instrumental assessment of dynamic balance showed significance for all parameters considered for G-Hun, while G-Conv showed no statistically significant results. Comparison between groups showed significance for open-eye sway area (p = 0.006), open-eye COP path (p = 0.002), trunk movements (p = 0.035), trunk sway in the midlateral direction (p = 0.001), and mean speed of COP sway in the antero-posterior direction (p = 0.035) (Table 4).

Table 4. Intra-group and inter-group analysis of instrumental assessment of the static and dynamic conditions of the whole sample.

	G-Hun				G-Conv		
	T0 Mediana (IQR)	T1 Mediana (IQR)	p Value	T0 Mediana (IQR)	T1 Mediana (IQR)	p Value	<i>p</i> Value G-Huv vs. G-Conv
Static Condition	Mediana (IQK)	Mediana (IQK)	•	Mediana (IQK)	Mediana (IQK)	•	G-Huv vs. G-Conv
Area-EC [cm ²]	4.96 [4.17-6.50]	2.67 [1.87-6.08]	<i>p</i> = 0.169	7.73 [5.98–9.5]	7.73 [5.98–9.5]	p = 0.142	p = 0.186
Area-EO [cm ²]	2.50 [2.05-3.34]	1.99 [1.18–3.58]	p = 0.959	1.17 [0.95–3.1]	1.35 [1.17–3.1]	p = 0.155	p = 0.361
Romberg Index	0.37 [0.36-0.55]	0.86 [0.37-1.40]	p = 0.471	0.23 [0.14-0.33]	0.23 [0.14-0.47]	p = 0.241	p = 0.047
COP path-EO [cm]	49.78 [36.02–70.64]	42.96 [31.00-61.78]	p = 0.333	33.53 [28.25–35.79]	35.32 [29.3–35.79]	p = 0.177	p = 0.303
COP path-EC [cm]	64.38 [49.44–118.26]	60.68 [49.56-88.22]	p=0.169	62.89 [46.76-115.83]	62.89 [46.76-115.83]	p = 0.220	p = 0.119
Trunk movement-EO [deg/s ²]	0.05 [0.04–0.07]	0.05 [0.05-0.07]	p = 0.735	0.04 [0.04–0.06]	0.04 [0.04-0.08]	p = 1.000	p = 0.569
Trunk movement-EC [deg/s ²]	0.05 [0.05–0.12]	0.05 [0.05-0.05]	p = 0.075	0.06 [0.04-0.1]	0.06 [0.04–0.01]	p = 0.237	p = 0.277
Trunk sway range AP-EO [deg]	2.80 [2.12–3.22]	3.03 [2.31–6.97]	p = 0.059	2.12 [2.1–2.97]	2.12 [2.1–2.97]	p = 0.256	p = 0.186
Trunk sway range AP-EC [deg]	3.07 [2.42–4.16]	2.78 [2.24–3.32]	p = 0.575	3.21 [2.52-4.09]	3.21 [2.52-4.09]	p = 0.242	p = 0.608
Trunk sway range ML-EO [deg]	1.25 [0.83–1.54]	1.28 [0.97-2.07]	p = 0.507	0.81 [0.43.1.17]	0.81 [0.45–1.17]	p = 0.158	p = 0.691
Trunk sway range ML-EC [deg]	1.41 [1.26–1.90]	1.31 [0.98–2.03]	p = 0.507	1.21 [0.86–1.43]	1.21 [0.86–1.43]	p = 0.189	<i>p</i> = 0.331
COP sway range AP-EO [cm]	1.96 [1.83–2.67]	1.75 [1.36–3.87]	p = 0.959	2.96 [2.22–3.43]	2.96 [2.22–3.43]	p = 0.164	p = 0.424
COP sway range AP-EC [cm]	2.35 [2.21–3.01]	2.47 [2.14–2.77]	p = 0.878	1.77 [1.5–2.23]	1.78 [1.5–2.23]	p = 0.157	p = 0.424
COP sway range ML-EO [cm]	3.63 [2.59–4.41]	2.83 [2.31–3.48]	p = 0.92	3.74 [2.99–5.2]	3.74 [2.99–5.1]	p = 0.174	<i>p</i> = 0.026
COP sway range ML-OC [cm]	1.41 [1.27–2.12]	1.73 [1.10–2.29]	p = 0.959	1.21 [0.65–1.49]	1.30 [1.03–1.49]	p = 0.144	p = 0.691
Ratio of axes of the ellipse-EO [%]	54.43 [48.07–57.68]	39.93 [35.21–49.86]	p = 0.600	62.64 [50.72–71.79]	71.79 [60.55–71.9]	p = 0.182	p = 0.055
Ratio of axes of the ellipse -EC [%]	55.96 [46.60]	48.89 [46.46-73.37]	p = 0.646	60.90 [48.86-81.69]	60.90 [54.77-81.69]	p = 0.157	p = 0.119
Mean speed COP AP-EO [cm/s]	1.38 [1.16–1.82]	1.29 [0.95–1.84]	p = 0.721	0.86 [0.83–0.98]	0.98 [0.86–1.02]	p = 0.139	p = 0.361
Mean speed COP AP-EC [cm/s]	1.90 [1.48–4.06]	1.68 [1.56–1.96]	p=0.874	1.81 [1.41-4.02]	1.81 [1.41-4.02]	p = 0.157	<i>p</i> = 0.186
Mean speed COP ML-EO [cm/s]	0.77 [0.50–0.97]	0.66 [0.47-0.97]	p = 0.283	0.70 [0.38–0.71]	0.70 [0.38–0.71]	p = 0.177	<i>p</i> = 0.018
Mean speed COP ML-EC [cm/s]	0.93 [0.66–1.54]	0.87 [0.67–1.87]	p = 0.859	0.99 [0.8–1.19]	1.04 [0.99–1.19]	p = 0.128	<i>p</i> = 0.569
Dynamic Condition Area-EO [cm ²]	38.47 [17.95-44.66]	3.06 [2.44–10.33]	<i>p</i> = 0.006	39.50 [27.06-66.38]	39.50 [22.08-66.38]	<i>p</i> = 0.177	<i>p</i> = 0.006
COP path-EO [cm]	85.00 [49.94–115.41]	28.17 [17.19–30.82]	p = 0.004	94.26 [91.26–125.6]	94.26 [91.26–125.6]	p = 0.240	p = 0.002
Trunk movement-EO [deg/s ²]	0.08 [0.08-0.16]	0.06 [0.05–0.07]	p = 0.028	0.08 [0.07–0.11]	0.08 [0.07-0.11]	p = 0.347	<i>p</i> = 0.035
Trunk sway range AP-EO [deg]	4.40 [2.70–5.01]	2.87 [2.37-4.20]	<i>p</i> = 0.248	3.96 [3.45-4.09]	3.96 [3.45-4.09]	<i>p</i> = 0.184	<i>p</i> = 0.459
Trunk sway range ML-EO [deg]	4.97 [2.96–5.91]	1.89 [1.48-2.45]	<i>p</i> = 0.005	2.37 [1.92–5]	2.37 [1.92–5]	p = 0.664	<i>p</i> = 0.001
COP sway range AP-EO [cm]	7.16 [5.06–9.21]	3.23 [2.42–5.04]	<i>p</i> = 0.059	7.82 [7.11-8.9]	7.11 [5.73-8.9]	<i>p</i> = 0.378	<i>p</i> = 0.134
COP sway range ML-EO [cm]	6.32 [4.32–7.41]	2.07 [1.55–3.81]	<i>p</i> = 0.013	7.59 [5.6–10.38]	7.59 [5.6–10.38]	p = 0.157	<i>p</i> = 0.093
Mean speed COP AP-EO [cm/s]	2.49 [0.95–2.82]	0.56 [0.33-0.62]	p = 0.012	2.42 [1.41–3.11]	2.42 [1.41-3.11]	p = 0.124	<i>p</i> = 0.035
Mean speed COP ML-EO [cm/s]	1.44 [0.93–2.23]	0.59 [0.34–0.78]	<i>p</i> = 0.021	1.81 [1.36–2.54]	1.81 [1.36–2.54]	<i>p</i> = 0.237	<i>p</i> = 0.055

G-Hun: experimental group G-Conv: conventional group; EO: eyes open; EC: eyes closed; COP: centre of pressure; AP: antero-posterior; ML: medio-lateral; In bold the significant results for p < 0.05.

4. Discussion

Evidence from the literature show that balance-specific treatment in elderly subjects undergoing knee replacement had positive effects on proprioception, postural control, balance, and coordination [53]. A meta-analysis showed that balance-specific treatment improves motor performance, i.e., balance and walking, compared to conventional (i.e., non-balance-specific) treatment alone [31]: according to the literature, traditional rehabilitation treatment alone would not be sufficient to improve balance in this type of patient [54].

So far, there is no work in the literature using robotic balance rehabilitation for patients with OA, so it is difficult to compare the results obtained from this study with those already published.

Data analysis reported that patients undergoing balance-specific treatment with the Hunova[®] showed a significant improvement in dynamic balance and walking, both in terms of walking speed and distance travelled, compared to the group of patients undergoing conventional rehabilitation alone. These data were also confirmed by the results of the instrumental assessment, especially in its dynamic component. In this case, data analysis showed a marked improvement in dynamic balance in the group of patients undergoing rehabilitation with Hunova[®], both compared to baseline and, for some specific parameters, compared to the conventional rehabilitation group. In the latter case, in fact, patients in the Hunova[®] group showed a significant improvement, especially in the reduction of swaying, the reduction of swaying, and the reduction of trunk movements.

These results could be due to the fact that through the use of Hunova[®], intervention training based on perturbation, proprioception, and load perception was more effective than conventional rehabilitation intervention alone.

The analysis of the results revealed two other interesting things: the first is that patients undergoing a hip replacement and rehabilitation with Hunova[®] showed a significant improvement in symptoms, pain, quality of life, and overall treatment efficacy compared to the group of patients undergoing the same surgery and conventional rehabilitation alone. The second is that when considering fatigue, patients in the Hunova[®] group showed a significant reduction in fatigue in both the motor and cognitive components. These results confirm what Castelli and colleagues [55] have already showed, albeit in a different population undergoing robotic rehabilitation with Hunova[®].

This study showed that elderly patients who underwent prosthetic hip and knee replacement surgery had a significant improvement in terms of not only walking but also in the reduction of postural oscillations, and consequently showed greater stability during dynamic balance. These elements leading to improved balance performance and a reduced risk of falling. Furthermore, this study shows that fatigue, which can be a contributing factor to falls in elderly subjects, is also reduced in those patients who have undergone specific treatment for balance disorders with the Hunova[®] platform.

Several studies have reported that a specific rehabilitation treatment for balance and walking is effective in patients underwent surgery after OA [17,18,31,33]. To the best of our knowledge, to treat those patients, beyond conventional physical therapy, technological rehabilitation is carried out mainly by means of end-effectors and exoskeletons [25–28].

Some aspects need to be taken into account while analyzing these findings. First of all, because these are preliminary findings, further research will be required to validate the original theory. The sample size is the study's primary limitation. However, as previously mentioned, the Julious' rules for Pilot Clinical Trials [51] were used to estimate the inclusion of 12 patients each group, for a total population of 24 people. A further constraint on the research is the absence of post-protocol and post-discharge follow-up. In fact, even after being released from rehabilitation, certain longitudinal studies indicate that function may continue to improve [56].

5. Conclusions

This is the first study involving a robotic platform in the recovery of those orthopaedic patients. These preliminary findings provide a crucial foundation for more research.

Hunova[®] may be a useful tool for enhancing elderly persons' balance with hip or knee replacement after OA.

The risk of falls in older persons may be reduced by using this technological rehabilitation therapy, which can improve motor performance, minimize fatigue, and improve dynamic balance and ambulation.

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Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available in the article.

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