



## Effectiveness Comparison of Extracorporeal Shock Wave Therapy and Conventional Physical Therapy Modalities in Primary Knee Osteoarthritis

Primer Diz Osteoartritinde Konvansiyonel Fizik Tedavi Modaliteleri ve Ekstrakorporeal Şok Dalga Tedavisinin Etkinliklerinin Karşılaştırılması

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### Abstract

**Objective:** In this study, it was aimed to compare the effects of radial-extracorporeal shockwave treatment (r-ESWT) and conventional physical therapy (PT) modalities treatments on pain, joint range of motion (ROM), functional status and walking speed in patients with primary knee osteoarthritis (KOA).

**Materials and Methods:** A total of 51 patients (26 patients in the ESWT group and 25 patients in the combined PT group) diagnosed with stage 2 or stage 3 primary KOA according to the Kellgren-Lawrence staging were included in the study. ESWT protocol of 2.0 bar, 0.25 mJ/mm<sup>2</sup>, and ten beats/sec frequency was used once a week for a total of three sessions. In the PT group, hot-pack 30 min/day, transcutaneous electrical nerve stimulation 30 min/day, and ultrasound 10 min/day were performed as a combination therapy for five sessions a week and in a total of three weeks. Besides, a therapeutic home exercise program was administered to both groups. The groups were assessed on days 0, 10, and 21 using the parameters of visual analog scale (VAS), Western Ontario McMaster Universities Osteoarthritis index (WOMAC), joint ROM measurements, and the Timed "Up & Go" (TUG) test.

**Results:** No statistically significant differences were determined between the groups regarding the pretreatment and 10-day and 21-day posttreatment scores, VAS, WOMAC, joint ROM, and TUG parameters ( $p>0.05$ ). In intra-group evaluations, statistically significant improvements were determined when the 10-day and 21-day values of VAS, WOMAC, joint ROM, and TUG parameters were compared to the pretreatment values ( $p<0.05$ ).

**Conclusion:** r-ESWT and conventional PT were determined to have similar effects on primary KOA treatment. However, further and comprehensive studies are needed to reach more precise and accurate results.

**Keywords:** Extracorporeal shockwave therapy, conventional physical therapy modalities, primary knee osteoarthritis

### Öz

**Amaç:** Bu çalışmada, primer diz osteoartriti (DOA) tanılı hastalarda, radyal-ekstrakorporeal şok dalga tedavisi (r-ESWT) ve konvansiyonel fizik tedavi (FT) modaliteleri tedavilerinin ağrı, eklem hareket açıklığı (EHA), fonksiyonel durum ve yürüme hızı üzerindeki etkilerinin karşılaştırılması amaçlanmıştır.

**Gereç ve Yöntem:** Çalışmaya, Kellgren-Lawrence evlendirmesine göre evre 2 ve 3 primer DOA tanılı 51 hasta (26 hasta ESWT grubu, 25 hasta kombine FT grubu) dahil edildi. ESWT protokolü, 2,0 bar, 0,25 mJ/mm<sup>2</sup> ve 10 atım/sn frekansında, haftada bir seans olmak üzere toplam 3 seans uygulandı. FT grubuna ise haftada 5 seans toplam 3 hafta 20 dk/gün hot-pack, 30 dk/gün transkutanöz elektriksel sinir stimülasyonu, 10 dk/gün ultrason kombine tedavisi uygulandı. Her iki gruba terapötik ev egzersiz programı verildi. Gruplar 0., 10. ve 21. günlerde vizüel analog skalası (VAS), Western Ontario ve McMaster Üniversitesi Osteoartrit indeksi (WOMAC), EHA ölçümü ve the Timed "Up & Go" (TUG) testi parametreleri ile değerlendirildi.

**Bulgular:** Gruplar arasında tedavi öncesi ile tedavi sonrası 10. ve 21. gün skorlarında VAS, WOMAC, EHA ve TUG parametrelerinde istatistiksel olarak anlamlı bir fark saptanmadı ( $p>0,05$ ). Grup içi değerlendirmede ise; her iki grupta da tedavi öncesi değerlerine göre 10. ve 21. günlerde VAS, WOMAC, EHA ve TUG parametrelerinde istatistiksel olarak anlamlı bir iyileşme gözlemlendi ( $p<0,05$ ).

**Sonuç:** Primer DOA tedavisinde r-ESWT, konvansiyonel FT ile benzer etkinlik göstermiştir. Ancak, daha kesin ve doğru sonuçlara ulaşmak için daha ileri ve geniş kapsamlı çalışmalara ihtiyaç vardır.

**Anahtar kelimeler:** Ekstrakorporeal şok dalga tedavisi, konvansiyonel fizik tedavi modaliteleri, primer diz osteoartriti

## Introduction

Osteoarthritis is the most prevalent joint disorder in the developed world. The knee is the most commonly involved joint, and knee osteoarthritis (KOA) is the leading cause of physical functional loss and chronic disability, particularly in the elderly population (1). Due to the prolongation of populations' life expectancies, its increased incidence and prevalence have made KOA a significant public health problem (2).

Today, even though KOA's definitive treatment is not yet possible, patients' quality of life can be improved by measures such as reducing pain, increasing mobility, and decreasing disabilities. The pain-relieving effects of pharmacological agents used in KOA treatment are generally limited (3), and they are frequently associated with severe side effects, including bleeding and gastrointestinal ulcers (4). Besides, complementary treatments such as local injections, acupuncture, transdermal patches, cupping therapy, exercise, and laser therapy are used for treating KOA. However, they are not sufficient to take chronic, severe KOA pain under control (5). Even though surgical treatment is usually effective in treating patients with advanced KOA, some elderly patients with limiting comorbidities might not be suitable for such a treatment approach (6). Besides its use in many orthopedic disorders with chronic pain (5,7,8), extracorporeal shockwave treatment (ESWT), which is a non-invasive method performed by administering shock waves from outside the body, can be used as an alternative treatment with a low number of complications in KOA patients (5,9). Various animal studies on KOA treatment have reported that ESWT delayed osteoarthritis progression, improved motor dysfunction, reduced pain, provided regression of osteoarthritis, and manifested chondroprotective effects (9-12). Besides a limited number of recently conducted human studies reporting improvements in pain relief and knee functions with ESWT (7,13,14), there are other studies reporting that it was ineffective (15). The number of studies comparing ESWT therapy with conventional physical therapy (PT) is not enough (16).

In this study, we aimed to compare ESWT with conventional modalities [hot-pack (HP), ultrasound (US), and transcutaneous electrical nerve stimulation (TENS)] regarding their effectiveness on pain, function and joint range of motion (ROM) in patients diagnosed with primary KOA [Kellgren-Lawrence (K-L), stages 2 and 3].

## Materials and Methods

The study was designed as a prospective, randomized study. A total of 54 patients who had presented to the Physical Medicine and Rehabilitation Outpatient Clinic in Atatürk University Medical Faculty Research Hospital with the complaint of knee pain and were diagnosed with primary KOA according to the American College of Rheumatology's (ACR) clinical/radiological diagnostic criteria and were at K-L 2-3 stages were included in the

study (17). This study was approved by the Ethical Committee of the Atatürk University Medical Faculty (22.04.2019/03; 24). All patients were informed following the Declaration of Helsinki about the study's purpose and procedures to be performed. With computer-assisted simple randomization, patients were divided into two equal groups as group 1 (n=27, radial-ESWT group) and group 2 (n=27, conventional PT modalities group). Written informed consent was obtained from all patients before participating in the study. One patient in the ESWT group and two patients in the PT group quit participating in the study due to personal reasons. As a result, 51 patients were included, consisting of 26 patients in group 1 and 25 in group 2.

The study's inclusion criteria were being diagnosed with primary KOA following the ACR's clinical/diagnostic criteria, being within the age range of 40-70 years, and having radiological signs of knee degeneration (stages 2 or 3 according to the K-L staging). The study's exclusion criteria were to have a pathology that prevented ambulation, a history of spinal stenosis, evidence of a neurological disorder in history or physical examination, a disorder (inflammatory or metabolic) that could cause secondary osteoarthritis, intra-articular knee injections within the last one year, non-steroidal anti-inflammatory drugs (NSAIDs) within the last one week, and a history of surgery for the knee joint.

## Interventions

In group 1, a total of three ESWT sessions, one per week, with 3000 beats, 10 Hz, 2.0 bar, 0.125 mJ/mm<sup>2</sup> were performed as the ESWT protocol. In group 1, the first treatment session was on the first day of the study, the second treatment session was on the 8<sup>th</sup> day of the study, and the third treatment session was on the 15<sup>th</sup> day of the study. The first 1000 beats were applied at the knee joint capsule (trigger points) at the supine position and the knee joint at 90° flexion (Figure 1). The successive 2000



**Figure 1.** Application of ESWT to trigger points in knee osteoarthritis  
ESWT: Extracorporeal shockwave treatment

beats were applied at the quadriceps muscle region and the peri-articular area outside the popliteal region while the patient was lying at the supine position and the knee joint at 30° flexion (Figure 2).

In group 2, a combined protocol, involving 20 minutes of HP, 30 minutes of TENS (with 20-60 microseconds pulse duration, 95 Hz stimulus frequency, and the intensity adjusted according to the patient, and not to cause contractions), and 10 minutes of US (with a dose of 1 watt/cm<sup>2</sup>) was applied five sessions a week and 15 sessions in total. Besides, therapeutic home exercise programs for the knee, such as joint ROM, stretching, isometric strengthening, and isotonic strengthening exercises, were practically taught and practiced after presenting an exercise form-sheet with pictures and explanations in both groups. This home exercise program is suggested as 30 minutes every day.

### Clinical Evaluation

Visual analog scale (VAS) of for pain, knee joint ROM, Western Ontario and McMaster Universities Osteoarthritis index (WOMAC), and the Timed "Up & Go" (TUG) tests were used for assessment of patients' pain and functional status. All patients were evaluated using these parameters before treatment (0-day), the 10<sup>th</sup> day, and the 21<sup>st</sup> day after the treatment initiation. VAS pain evaluated the patients' mean resting, activity, and nocturnal pain levels (18). ROM measurements were made actively and passively by a goniometer according to the neutral position 0° method. The WOMAC index and the TUG test were used for the assessment of patients' functional status. WOMAC consists of three subscales and 24 items as Pain (5 items), Stiffness (2 items), and Physical Function (17 items). In its Likert-scale version, the scores are summed up for each subscale's items within the following probable ranges: Pain: 0-20 points, Stiffness: 0-8 points, and Physical Function: 0-68 points (19). For



**Figure 2.** Application of ESWT to quadriceps muscle region in knee osteoarthritis

ESWT: Extracorporeal shockwave treatment

the TUG test, the individuals were asked to stand up from a fixed-arm chair while sitting with feet contacting the floor, walk three meters, turn back from the marked site at the end of three meters, walk back to the chair, and sit on the chair. The duration, recorded as seconds by a stopwatch, was started as soon as the individual's hips lost contact with the chair and stopped when they contacted the chair after turning back (20).

### Statistical Analysis

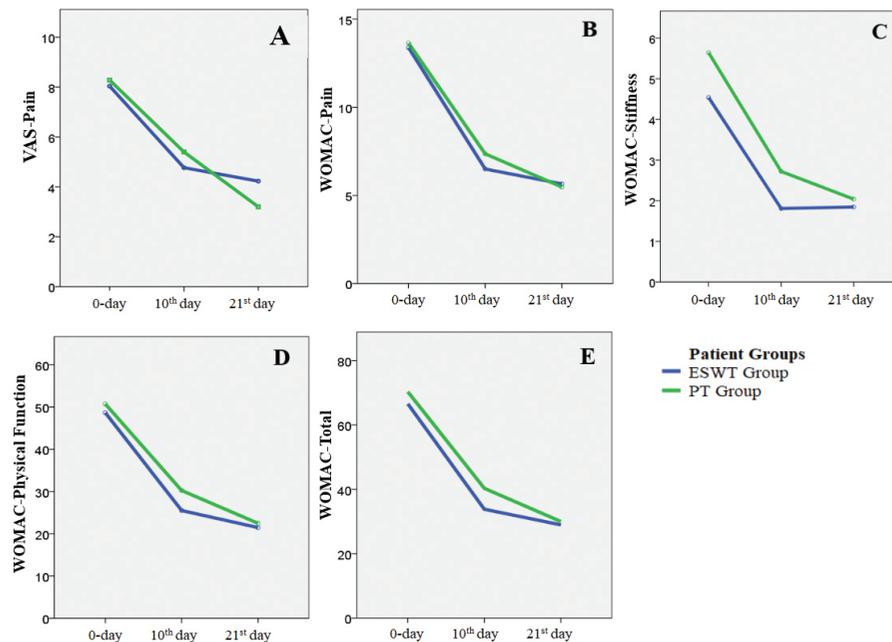
The study's data were evaluated for statistical analysis using the Statistical Package for Social Sciences for Windows, version 22 software. The normality of numerical data distribution was assessed by the Shapiro-Wilk and Kolmogorov-Smirnov tests. The general descriptive statistics of continuous variables such as mean, median, and standard deviation were obtained. The inter-group discrete distribution analyses were made using either chi-square or Fisher's Exact test analysis. For continuous variables' analysis of inter-group differences, the t-test for independent two groups was used for normally distributed data and the Mann-Whitney U test for data that did not have a normal distribution. Variables such as VAS pain, WOMAC, and TUG were intragroup compared using the Analysis of Variance for data showing a normal distribution and the Freadman test for data that were not normally distributed. The group differences were determined using post-hoc and Wilcoxon tests. The results' confidence interval was 95%, and  $p < 0.05$  was considered statistically significant.

### Results

No significant differences were present between the ESWT and PT groups regarding the demographic characteristics (Table 1). The patients' mean 0-day, 10<sup>th</sup> day, and 21<sup>st</sup> day ROM, VAS pain, WOMAC, and TUG values were evaluated in both groups.

Regarding intra-group comparisons, in both groups, significant differences were present between the 0-day and 10<sup>th</sup>-day values of all parameters ( $p < 0.05$ ). In the ESWT group, significant differences were present between the 10<sup>th</sup>-day and 21<sup>st</sup>-day values of WOMAC-PF, WOMAC-total, and TUG ( $p < 0.05$ ), whereas no significant differences were determined regarding other parameters. In the PT group, significant differences were present between the 10<sup>th</sup>-day and 21<sup>st</sup>-day values of VAS pain, WOMAC-pain, WOMAC-PF, WOMAC-total, right knee active flexion, left knee passive flexion, and TUG ( $p < 0.05$ ), whereas no differences were determined regarding other parameters (Table 2).

Regarding inter-group comparisons, no statistically significant differences were determined among the 0-day, 10<sup>th</sup>-day, and 21<sup>st</sup>-day values of all parameters except for the 0-day WOMAC-Stiffness value ( $p < 0.05$ ) (Table 3). The changing trends of 0-day, 10<sup>th</sup>-day, and 21<sup>st</sup>-day VAS pain and WOMAC values in both groups were shown in Figure 3.



**Figure 3.** Change graph of VAS pain (A), WOMAC-Pain (B), WOMAC-Stiffness (C), WOMAC-Physical Function (D), WOMAC-Total (E) scores of the groups on 0-day, 10<sup>th</sup> day and 21<sup>st</sup> day

VAS: Visual analog scale, WOMAC: Western Ontario McMaster Universities Osteoarthritis index, ESWT: Extracorporeal shockwave treatment, PT: Physical therapy

**Table 1. Comparison of the demographic characteristics of the groups**

Variables	ESWT (n=26)	PT (n=25)	p-value
Age (mean ± SD; min-max)	57.35±8.3 (42-70)	58.2±6.2 (48-67)	>0.05 <sup>a</sup>
<b>Gender</b>			
Male	4 (15.4%)	2 (8%)	>0.05 <sup>b</sup>
Female	22 (84.6%)	23 (92%)	>0.05 <sup>b</sup>
BMI (kg/m <sup>2</sup> ); (mean ± SD; min-max)	34.07±5 (25.59-44.44)	33.04±5.2 (22.23-45.79)	>0.05 <sup>a</sup>
<b>KOA involvement</b>			
Unilateral	6 (23.1%)	1 (4%)	>0.05 <sup>b</sup>
Bilateral	20 (76.9%)	24 (96%)	
<b>Right KOA diagnosis</b>			
Medial OA	14 (66.7%)	16 (66.7%)	>0.05 <sup>b</sup>
Medial+PF OA	7 (33.3%)	8 (33.3%)	
<b>Right KOA stage</b>			
Stage II	13 (50%)	17 (68%)	>0.05 <sup>b</sup>
Stage III	13 (50%)	8 (32%)	
<b>Left KOA diagnosis</b>			
Medial OA	18 (72%)	18 (72%)	>0.05 <sup>b</sup>
Medial+PF OA	7 (28%)	7 (28%)	
<b>Left KOA stage</b>			
Evre II	15 (57.7%)	16 (64%)	>0.05 <sup>b</sup>
Evre III	11 (42.3%)	9 (36%)	

n: Number of patients, ESWT: Extracorporeal shock wave therapy, PT: Physical therapy, BMI: Body mass index, KOA: Knee osteoarthritis, PF: Patello-Femoral, OA: Osteoarthritis, SD: Standard deviation, min-max: Minimum-maximum, \*p<0.05: Statistically significant difference between groups <sup>a</sup>Independent samples t-test, <sup>b</sup>chi-square (2x2) independency test

**Table 2. Intra-group comparisons of 0-day, 10<sup>th</sup> day and the 21<sup>st</sup> day mean values of the parameters for both groups**

	Groups	0-day	10 <sup>th</sup> day	21 <sup>st</sup> day	p-value
VAS	ESWT	8±1.8	4.8±3.1	4.2±3	<0.05 <sup>a,b</sup>
	PT	8.3±1.7	5.4±2	3.2±1.9	<0.05 <sup>a,b,c</sup>
WOMAC-pain	ESWT	13.4±2.5	6.5±3	5.7±3.4	<0.05 <sup>a,b</sup>
	PT	13.6±3.3	7.4±3.9	5.5±3.4	<0.05 <sup>a,b,c</sup>
WOMAC-stiffness	ESWT	4.5±2.1	1.8±1.6	1.8±1.3	<0.05 <sup>a,b</sup>
	PT	5.6±1.3	2.7±1.6	2±1.4	<0.05 <sup>a,b</sup>
WOMAC-PF	ESWT	48.7±9.5	25.5±9.6	21.5±10.3	<0.05 <sup>a,b,c</sup>
	PT	50.7±9.4	30.2±13.2	22.5±11.1	<0.05 <sup>a,b,c</sup>
WOMAC-total	ESWT	66.6±12.3	33.8±13.3	29±13.9	<0.05 <sup>a,b,c</sup>
	PT	70.3±13.2	40.3±18.2	30±15.4	<0.05 <sup>a,b,c</sup>
Right knee Flexion-active	ESWT	111±13	115±12	115±14	<0.05 <sup>a,b</sup>
	PT	108±16	112±14	116±12	<0.05 <sup>a,b,c</sup>
Right knee Flexion-passive	ESWT	125±1	129±12	130±11	<0.05 <sup>a,b</sup>
	PT	123±12	124±12	130±9	<0.05 <sup>b,c</sup>
Left knee Flexion-active	ESWT	107±11	113±10	116±10	<0.05 <sup>a,b</sup>
	PT	108±13	110±16	117±13	<0.05 <sup>a,b,c</sup>
Left knee Flexion-passive	ESWT	122±8	129±7	131±6	<0.05 <sup>a,b</sup>
	PT	121±13	125±11	130±11	<0.05 <sup>a,b,c</sup>
TUG (sec)	ESWT	12.5±3.4	10.1±2.5	9.6±2.2	<0.05 <sup>a,b,c</sup>
	PT	13.7±5	10.9±2.3	10.1±2.1	<0.05 <sup>a,b,c</sup>

VAS: Visual analog scale, WOMAC: Western Ontario McMaster Universities Osteoarthritis index, PF: Physical function, sec: second, <sup>a</sup>Repeated Measures ANOVA, <sup>b</sup>Freadman test. Values are given as mean ± standard deviation.  
<sup>a</sup>Difference between 0-day and 10<sup>th</sup> day, <sup>b</sup>Difference between 0-day and 21<sup>st</sup> day, <sup>c</sup>Difference between 10<sup>th</sup> day and 21<sup>st</sup> day, p<0.05: Statistically significant difference

## Discussion

KOA is the leading cause of disability and joint pain in adults and is mainly characterized by exacerbating chronic pain due to aggravated central sensitization and decreased physical function (1,21). Even though the exact treatment mechanism of ESWT in KOA has not been fully revealed in the literature, several hypotheses have been proposed on this subject. ESWT has been suggested to create an analgesic effect through a reflex mechanism by inducing axon excitability and inhibiting the non-myelinated sensory nerve fibers (22). Besides, it has been suggested in several animal studies that the analgesic effect might have occurred due to the reduction of calcitonin gene-related peptide and substance P, which are significant neuropeptides of nociceptive pathways in the target tissues and dorsal root ganglions. On the other hand, it was stated that ESWT might have contributed to healing by reducing KOA progression, cartilage disruption, and chondrocyte apoptosis through reduction of nitric oxide levels, leading to local endorphin release and reformation of subchondral bone (16). ESWT has been reported to be superior to placebo-ESWT in pain reduction and improvements in knee functions and TUG values (16,23-25). Kim et al. (13) in their study on K-L grade 2 and 3 KOA patients, reported that ESWT at a moderate-level

energy intensity (0.093 mJ/mm<sup>2</sup>) had led to more improved results regarding pain relief and functional restoration when compared to ESWT at a low-level energy intensity (0.040 mJ/mm<sup>2</sup>). They suggested that the higher energy intensity had significantly inhibited the non-myelinated nerve fibers and had produced a more significant analgesic effect. In a meta-analysis review study, Wang et al. (26) reported that ESWT had a positive impact up to 12 months on the analgesic effect evaluated with VAS pain and the physical function evaluated with WOMAC. Besides, even though they reported that ESWT was more effective when used with moderate-level intensities over 0.093 mJ/mm<sup>2</sup>, they stated that the ESWT frequency and the dose levels required for achieving maximal improvement were not clear. On the other hand, Imamura et al. (15) in their study on primary KOA patients with K-L grades 2-4, reported that ESWT with 2000 beats, 0.10-0.16 mJ/mm<sup>2</sup> energy intensity, 2.5-4.0 bar pressure, and 8 Hz frequency in patients with severe KOA was effective on WOMAC-Pain values, but ineffective on VAS pain scores, and that higher energy intensities would have been required for treatment success.

Our study determined that both treatments significantly improved KOA patients' ROM, pain, and function values on the 10<sup>th</sup> and 21<sup>st</sup> days after the treatment. In the ESWT group, improvements of function and TUG values were determined

**Table 3. Comparisons of the parameters of both groups at 0-day, 10<sup>th</sup> day and the 21<sup>st</sup> day**

	ESWT	PT	p-value
	Mean ± SD	Mean ± SD	
VAS (0-day)	8±1.8	8.3±1.7	>0.05 <sup>b</sup>
VAS (10 <sup>th</sup> day)	4.8±3.1	5.4±2	>0.05 <sup>b</sup>
VAS (21 <sup>st</sup> day)	4.2±3	3.2±1.9	>0.05 <sup>b</sup>
WOMAC-pain (0-day)	13.4±2.5	13.6±3.3	>0.05 <sup>b</sup>
WOMAC-pain (10 <sup>th</sup> day)	6.5±3	7.4±3.9	>0.05 <sup>a</sup>
WOMAC-pain (21 <sup>st</sup> day)	5.7±3.4	5.5±3.4	>0.05 <sup>a</sup>
WOMAC-stiffness (0-day)	4.5±2.1	5.6±1.3	<0.05 <sup>*b</sup>
WOMAC-stiffness (10 <sup>th</sup> day)	1.8±1.6	2.7±1.6	>0.05 <sup>b</sup>
WOMAC-stiffness (21 <sup>st</sup> day)	1.8±1.3	2±1.4	>0.05 <sup>b</sup>
WOMAC-PF (0-day)	48.7±9.5	50.7±9.4	>0.05 <sup>b</sup>
WOMAC-PF (10 <sup>th</sup> day)	25.5±9.6	30.2±13.2	>0.05 <sup>a</sup>
WOMAC-PF (21 <sup>st</sup> day)	21.5±10.3	22.5±11.1	>0.05 <sup>a</sup>
WOMAC-total (0-day)	66.6±12.3	70.3±13.2	>0.05 <sup>b</sup>
WOMAC-total (10 <sup>th</sup> day)	33.8±13.3	40.3±18.2	>0.05 <sup>a</sup>
WOMAC-total (21 <sup>st</sup> day)	29±13.9	30±15.4	>0.05 <sup>a</sup>
Right knee Flexion-active (0-day)	111±13	108±16	>0.05 <sup>b</sup>
Right knee Flexion-passive (0-day)	125±11	123±12	>0.05 <sup>b</sup>
Left knee Flexion-active (0-day)	107±11	108±13	>0.05 <sup>a</sup>
Left knee Flexion-passive (0-day)	122±8	121±13	>0.05 <sup>b</sup>
Right knee Flexion-active (10 <sup>th</sup> day)	115±12	112±14	>0.05 <sup>b</sup>
Right knee Flexion-passive (10 <sup>th</sup> day)	129±12	124±12	>0.05 <sup>b</sup>
Left knee Flexion-active (10 <sup>th</sup> day)	113±10	110±16	>0.05 <sup>b</sup>
Left knee Flexion-passive (10 <sup>th</sup> day)	129±7	125±11	>0.05 <sup>b</sup>
Right knee Flexion-active (21 <sup>st</sup> day)	115±14	116±12	>0.05 <sup>b</sup>
Right knee Flexion-passive (21 <sup>st</sup> day)	130±11	130±9	>0.05 <sup>b</sup>
Left knee Flexion-active (21 <sup>st</sup> day)	116±10	117±13	>0.05 <sup>b</sup>
Left knee Flexion-passive (21 <sup>st</sup> day)	131±6	130±11	>0.05 <sup>b</sup>
TUG (sec) (0-day)	12.5±3.4	13.7±5	>0.05 <sup>b</sup>
TUG (sec) (10 <sup>th</sup> day)	10.1±2.5	10.9±2.3	>0.05 <sup>b</sup>
TUG (sec) (21 <sup>st</sup> day)	9.6±2.2	10.1±2.1	>0.05 <sup>a</sup>

SD: Standard deviation, VAS: Visual analog scale, WOMAC: Western Ontario McMaster Universities Osteoarthritis index, PF: Physical function, TUG: The Timed "Up & Go", sec: second, \*p<0.05: Statistically significant difference between groups <sup>a</sup>Independent samples t-test <sup>b</sup>Mann-Whitney U test

to continue between 10-21 days. Thus, we determined that the significant improvement effect of ESWT on the ROM and pain values started faster than those of the PT. Besides, ESWT's effect on function continued increasingly until the 21<sup>st</sup> day. In their study, Chen et al. (27) reported that ESWT ameliorated the knee pain and improved the joint ROM, and following every ESWT session, they observed that the improvement in ROM occurred rapidly, consistent with the pain and ROM values in our study. Our study determined that all parameters progressively improved until the 21<sup>st</sup> day in the PT Group, and no significant differences were present between the treatment groups on both the 10<sup>th</sup> and 21<sup>st</sup> days.

In our study, ESWT was performed with 3000 beats and moderate-level (0.125 mJ/mm<sup>2</sup>) energy intensity once a week in KOA patients with K-L grades of 2-3. The significant improvements observed in both the VAS pain scores and function values were consistent with the literature (24,25). On the other hand, since the number of beats was less (2000 beats) and KOA patients with a K-L grade of 4 were included in Imamura et al.'s (15) study, their results might not have been similar to our study. Therefore, we suggest that a sufficient energy intensity dosing, number of beats, and application frequency should be set up to achieve maximal-level effectiveness in ESWT.

In the meta-analysis study performed by Wang et al. (26), in the four articles considering ESWT's reliability, pain and discomfort were reported to occur due to minor complications such as mild bruising, temporary soft tissue swelling, or temporary flushing after ESWT. In the same study, five articles reported no clinical neuromuscular, equipment-related, or systemic side effects after ESWT. On the other hand, degenerative hyaline cartilage changes were reported to be associated with energy intensity levels over 0.50 mJ/mm<sup>2</sup> in rats (28). We determined no significant local or systemic side effects of ESWT in our study. However, some patients in the ESWT group expressed slightly increased pain in the application area at the onset of treatment, decreasing afterward during and after the session. Therefore, ESWT can be used as an alternative treatment method in patients, particularly the elderly, who can not use NSAIDs because of their gastrointestinal and cardiovascular side effects due to its relative reliability and low-degree side effects. Besides, ESWT might be a non-invasive, effective, low complication rate, and reliable treatment option with lower cost and not necessitating hospitalization when compared to other conservative treatment methods and surgery (29).

Our study's limitations were the lack of a control group and absence of study groups without exercise therapy, receiving only-ESWT and sham-ESWT treatments. Moreover, because our study covered 21 days only, we could not evaluate the long-term efficacy of ESWT in KOA.

## Conclusion

In conclusion, we determined that both ESWT and conventional PT applications on pain, ROM and function were similarly effective in KOA treatment. When its faster starting effects on pain and joint ROM and other potential advantages are considered, ESWT can be an effective, safe, and promising alternative treatment option. However, placebo-controlled studies with more extensive participation involving long-term follow-up periods are required to determine the optimal energy dose, number of beats, and application frequency.

## Ethics

**Ethics Committee Approval:** This study is approved by the Atatürk University Ethics Committee with the date 22.04.2019 and decision number 24.

**Informed Consent:** All patients were informed following the Declaration of Helsinki about the study's purpose and procedures to be performed.

**Peer-review:** Externally peer-reviewed.

## Authorship Contributions

Surgical and Medical Practices: Y.A., A.K., Concept: Y.A., A.K., Design: Y.A., A.K., Data Collection or Processing: Y.A., A.K., Analysis or Interpretation: Y.A., A.K., Literature Search: Y.A., A.K., Writing: Y.A., A.K.

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