

**Effects of Adjuvant Low-Dye Kinesio Taping, Adjuvant Sham Taping, or Extracorporeal Shockwave Therapy Alone in Plantar Fasciitis: A Randomized Double-Blind Controlled Trial**

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**Ethical disclosure**

28 Approval from the Ethics Committee of Gaziosmanpasa University Medical Faculty (no: 19-KAEK-  
29 063) was obtained.

30 The authors state that they have obtained appropriate institutional review board approval or have  
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43 All authors read and approved the final version of the manuscript.

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50

## 51 **Abstract**

### 52 **Aim**

53 Extracorporeal shockwave therapy (ESWT) is known as one of the most effective treatment methods  
54 in plantar fasciitis (PF). Low-dye taping, which is the most preferred method of banding treatments,  
55 provides an analgesic effect by correcting biomechanics. It was aimed to compare the efficacy of  
56 adjuvant low-dye kinesio-taping (KT), sham-taping, or extracorporeal shockwave therapy (ESWT)  
57 alone in plantar fasciitis (PF).

### 58 **Methods**

59 In this double-blind, sham-controlled study, forty-five patients with PF were randomized to 3-group  
60 (Group 1: ESWT plus low-dye KT, n=15; Group 2: ESWT plus Sham-taping, n=15; and Group 3:  
61 ESWT only, n=15) five-session ESWT were administrated. KT was performed and changed every 1-  
62 week for the ESWT sessions in Groups 1 and 2. The main outcome measures were the visual analog  
63 scale (VAS) change, the heel tenderness index (HTI), foot function index (FFI). The patients were  
64 evaluated at the beginning and end of the treatment and at the 4-week follow-up.

### 65 **Results**

66 The demographic characteristics and baseline outcomes between groups were similar ( $p>0.05$ ). VAS  
67 and HTI changes were observed in all three groups, there were no difference between groups.  
68 Repeated-measures ANOVA showed a significant interaction between the time and the groups in FFI-  
69 total ( $F_{3,919}=2.607$ ;  $p=.043$ ). At the 4-week follow-up, when Groups 1 and 2 were evaluated, the lower  
70 FFI-total, FFI-disability, and FFI-activity limitation were statistically significant in Group 1 ( $p=0.027$ ;  
71  $p=0.026$ ;  $p=0.029$ , respectively). When Group 1 and 3 were compared, the decrease in FFI-pain and  
72 FFI-activity limitation were significant in Group 1 ( $p=0.042$ ;  $p=0.035$ , respectively).

### 73 **Conclusions**

74 Low-dye KT, in addition to ESWT, is more effective than sham-taping and ESWT in pain relief and  
75 foot function improvement due to PF at a 4-week follow-up.

### 76 **Keywords**

77 Extracorporeal Shockwave Therapy (ESWT), Kinesio taping, Plantar fasciitis

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80 **What's known**

- 81     • Extracorporeal Shock Wave Therapy (ESWT) is generally used as a treatment for patients  
82         who do not benefit from conservative treatments. However, this treatment has an anti-  
83         inflammatory and anti-analgesic efficacy and has no effect on the impaired biomechanics of  
84         the foot.
- 85     • Low-dye banding method, has an effect on disrupted biomechanics, relieving the pain of the  
86         foot, causing the patient to have a better foot function.
- 87     • There are a few studies comparing the effect of taping and ESWT in the literature, and in most  
88         of the results obtained, the two groups were not superior to each other.

89 **What's new**

- 90     • The study is one of the pioneer studies in which the low-dye method was performed with  
91         kinesio taping.
- 92     • Four-session low-dye kinesio taping application with 5-session ESWT provided remarkable  
93         improvements in the foot functionality and these improvements were maintained in four  
94         weeks after the therapy, but similar improvements were not observed in pain and heel  
95         tenderness.

96

97 **List of abbreviations**

98

99 ESWT- Extracorporeal shockwave therapy

100 FFI- Foot function index

101 HTI- Heel tenderness index

102 KT- Kinesio taping

103 NSAID- Non-steroidal anti-inflammatory drug

104 PF- Plantar fasciitis

105 PSFS- Patient-specific functional scale

106 VAS- Visual analog scale

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## 110 **Introduction**

111 One of the most common musculoskeletal pathology and pain causes of the foot is plantar heel pain <sup>1</sup>,  
112 and the most common cause of heel pain in adult ages is plantar fasciitis (PF). Patients feel severe pain  
113 in the first step they take after sitting for a long time or getting up and walking in the morning, and this  
114 pain is triggered by stretching the plantar fascia and carrying loads <sup>2</sup>. Studies have indicated that foot  
115 pain and stiffness are between 18% and 63%. The plantar fascia is considered to be the result of  
116 micro-rupture occurring at the adhesion of the calcaneal bone as a result of excessive use, such as long  
117 standing and running. The plantar fascia starts from the medial tubercle of the calcaneus and ends by  
118 adhering to the plantar surface of the metatarsophalangeal joint, proximal phalanx, and flexor tendon  
119 sheaths. When the fingers are extended, the plantar fascia is functionally shortened, and this helps  
120 supine the foot in the pre-swing phase during walking. During loading on foot, the plantar fascia  
121 provides shock absorption. Therefore, any change in the biomechanics of the foot can also cause  
122 plantar heel pain <sup>1 3 4</sup>.

123 Many conservative methods have been used in the treatment of PF. Anti-inflammatory drugs, physical  
124 therapy modalities (iontophoresis, ultrasound, extracorporeal shockwave therapy, electrical  
125 stimulation, cryotherapy, and whirlpool), manual therapy, stretching therapy, and external support  
126 (orthosis and taping) are the main treatment methods. While most of the treatment programs are used  
127 to suppress symptoms, orthosis, and taping are aimed at correcting bad biomechanics in the foot <sup>1 5 6</sup>.  
128 Extracorporeal shockwave therapy (ESWT) is a relatively new treatment method used to relieve heel  
129 pain and in other conditions, such as lateral epicondylitis, calcific tendinopathy of the shoulder,  
130 patellar tendinitis, PF, and delayed-union and non-union in long bones <sup>4 7 8</sup>.

131 Foot orthoses are a common treatment used for plantar heel pain, but due to the manufacturing  
132 process, it usually takes a few weeks between diagnosis and the onset of using orthosis. Therefore,  
133 short-term treatments, such as supportive taping, are used to alleviate symptoms in this intermediate  
134 period. Randomized-controlled studies have argued that low-dye taping, which is the most commonly  
135 used banding technique, is an effective pain relief method in treatment by supporting the medial arch <sup>1</sup>.  
136 Conversely, relatively few studies in the literature have discussed the use of kinesio taping (KT),  
137 which is another method of taping in PF treatment <sup>2 9-11</sup>. Although low-dye taping and KT were found

useful in the early period in the treatment of PF, no randomized-controlled trials in which the KT application with the low-dye method was studied on this patient population have been found in the literature. One of the aims of the present study is to explain whether low-dye KT is useful in patients with PF with a well-planned randomized-controlled study. Furthermore, the study aims to investigate the effect of the low-dye KT added to ESWT on pain and functionality. Within this information, the hypothesis in the study is that low-dye KT plus ESWT treatment applied to patients with PF will be more effective in pain and foot functionality than ESWT plus sham-taping and ESWT alone.

## **Material and Method**

### ***Trial design***

This study was designed as single-centered, double-blinded, sham-controlled, and randomized.

### ***Patient selection and interventions***

Forty-five patients (mean age:  $51.57 \pm 9.27$ ) who were admitted to the (Blind) University Physical Medicine and Rehabilitation Outpatient Rehabilitation Clinic with heel pain and diagnosed with PF were included in the study. The patients were randomly divided into three groups as Group 1 (ESWT plus low-dye KT), Group 2 (ESWT plus sham-taping), and ESWT alone. Randomization was done by using a computer program that included a randomized table of numbers, which was created by an independent individual who was blind in the recruitment and treatment procedures. Numbered cards with a random assignment and containing information about the group allocation in opaque, sealed envelopes were prepared by the same independent individual. The certified therapist opened the envelope and applied the procedure according to randomization group. The patients underwent 5-session of ESWT once a week for five consecutive weeks according to the treatment protocol. KT was applied at the end of each session. Low-dye KT was applied to Group 1 after each ESWT session, and sham-taping was applied to Group 2. The total applied taping session was 4, and no taping was done after the last ESWT. Taping was not applied to Group 3 after ESWT.

164 The inclusion criteria in the study were the following: (1) within the age range of 18–65, (2)  
165 feels pain when pressure is applied on the plantar fascia, (3) has radiographic imaging of  
166 calcaneal spur, (4) feels first step pain when waking up in the morning or after long-term  
167 resting, (5) experiences pain persistence despite other conservative methods (i.e., NSAID and  
168 exercise), and (6) without cognitive impairment and impaired consciousness that could prevent  
169 the patient from expressing independent and informed consents. The exclusion criteria were as  
170 follows: feels heel pain for more than six months; experiences treatment with intra-articular  
171 injection (corticosteroids or corticosteroids/anesthetic) in the last three months; with a history of  
172 rheumatological disease, coagulopathy, thrombophlebitis, neoplasia, and systemic inflammatory  
173 diseases, has a surgical history from the foot or lumbar region; has lumbar radiculopathy  
174 symptoms, allergic to kinesiotape, and reluctant to participate in the study.

175 The study was conducted after approval from the Ethics Committee of (Blind)University  
176 School of Medicine in accordance with the Declaration of Helsinki (approval number:19-  
177 KAEK-063). It was registered on the ClinicalTrials.gov, and the registration number is  
178 NCT(**Blind**). Oral and written informed consents were obtained from all the patients after the  
179 explanation of the interventions.

180 The ESWT device (EMS Swiss Dolorclast® Classic) was applied in the physical therapy unit,  
181 with a total of 5-session of 11-Hz frequency, 3000 shockwaves, and 2.5 bar energy density.  
182 During the application, the patients were asked to lie down in a prone position and keep their  
183 knee and hip joints in a neutral position. Using the ultrasound gel between the probe and the  
184 heel, the head of the ESWT device was applied downstream of the calcaneus. The target area is  
185 the most sensitive point of the medial calcaneus <sup>2</sup>. All the applications were performed by a  
186 physiotherapist trained to apply ESWT.

187 The material used in KT is Kinesio® Tex Tape (Finger Print), and it is an original tape  
188 developed by Kenzo Kase <sup>12</sup>. A trained and certified researcher applied KT in the patients in  
189 groups 1 and 2 (4-time in total, once every week after the each ESWT session). If the patient



190 did not experience any allergic conditions, then the KT was left on the patient's foot for one  
191 week. As the taping method, the therapy used in low-dye KT was preferred in the study of Chen  
192 et al <sup>13</sup>. While doing the low-dye KT, the area correction I technique described by Kase and the  
193 mechanical correction technique were used <sup>14</sup> (Figure 1a). In a supine position, the patient's foot  
194 should remain in the neutral position on the same line with the 2<sup>nd</sup> finger and the cruris. The first  
195 band starts from the 5<sup>th</sup> metatarsal and runs lateral to the foot and reaches to the first metatarsal  
196 from the back of the heel. The tension was made at a rate of 50% in the middle 1/3 of the tape.  
197 The four kinesio bands that will pass from the lateral to the medial of the sole of the foot are  
198 adhered by stretching 50% as they come from lateral to medial without stretching where they  
199 begin and adhere. Each of the four bands is applied in the same way, the remaining above half  
200 the previous tape. Before the 6th tape, the foot is brought to the extension and adhered to the  
201 dorsum from the lateral to the medial region by making a 50% tension in the middle 1/3. For  
202 Group 2, where sham KT was performed, 2 I bands were applied randomly without any tension  
203 (Figure 1b). In case of any side effects (such as skin irritation and allergic reaction), it is  
204 recommended that the tape be removed for patients in Groups 1 and 2.

## 206 ***Outcomes***

207 All evaluations were conducted by a blind investigator who did not know about the patient group  
208 assignment.

### 210 *Primary outcome*

211 The primary outcome of the study is the visual analog scale (VAS) change. The VAS is used to  
212 measure and monitor pain intensity. This is a 10-cm ruler that writes painlessness on one end and the  
213 most severe pain on the other. A patient scores his/her pain between 0 and 10.

### 215 *Secondary outcomes*

## 216 *Heel tenderness index*

217 The heel tenderness index (HTI) is a method scored by clinicians. The presence of pain is investigated  
218 by touching the point where patients describe pain in the heel by palpation. 0 points: no pain; 1 point:  
219 painful; 2 points: painful and winces; and 3 points: painful, winces, and withdraws <sup>2</sup>.

220

## 221 *Foot function index*

222 The foot function index (FFI) is a questionnaire used to understand the activity limitations of patients  
223 with foot problems and to evaluate their response to treatment. AFI is a commonly used foot-specific  
224 self-assessment scale that anyone can easily apply. The validity and reliability of non-systemic foot  
225 and ankle problems were demonstrated by Agel et al. The questionnaire consists of three subtitles:  
226 pain, disability, and activity limitation. Scores are given as a percentage, and a high score indicates  
227 impairment in pain, disability, and activity limitation <sup>15</sup>.

228 The patients were evaluated before treatment, at the end of treatment (after the fifth ESWT session),  
229 and with a 4-week follow-up. All the outcome measures were collected by the same investigator who  
230 was blinded to the patient grouping at the beginning of the study, at the end of treatment, and at a 4-  
231 week follow-up.

232

## 233 **Sample Size**

234 The sample size estimation was performed using the GPower V.3.1.7 (University of Kiel, Kiel,  
235 Germany). It was determined that 12 individuals for each group must have been recruited to detect a  
236 difference at a 5% type 1 error level with 95% power when the average expected value in the first  
237 group was 71.4, with a standard deviation of 19.8 at the baseline, and the average expected value in  
238 the second group was 41.4, with a standard deviation of 28.5 based on the VAS scores at post-  
239 treatment (1-week) reported in the previous research conducted by Radford et al. <sup>9</sup>, who evaluated the  
240 effectiveness of low-dye taping for plantar heel pain.

241

## 242 **Statistical Analysis**

Statistical analyses were performed through the SPSS version 25.0 program. The histogram and normality plots and the Shapiro-Wilk normality test were used to evaluate the distribution of variables before test selection. Descriptive analyses were compared with mean and standard deviation (SD) for numeric variables for the ordinal variables and Pearson's chi-squared test for categorical comparisons. The Mann-Whitney U test were used when evaluating variables between the groups. The comparison of the change in the measured values between the groups was made with repeated measure analysis of variance with time (baseline, after treatment and 4 weeks after treatment) and group (ESWT plus low-dye KT, ESWT plus sham-taping, and ESWT alone). For intra-group analysis, Friedman test was used for repeated comparisons and Wilcoxon signed-rank test was performed with a Bonferroni correction for pairwise comparisons. In addition, the confidence intervals (95% CI) were calculated using an Excel spreadsheet <sup>16</sup>. In all analyses, the p-value lower than 0.05 was considered statistically significant.

## Results

Patient recruitment and follow-up are summarized in the Consolidated Standards of Reporting Trials (CONSORT) diagram of the study (Figure 2). Because three of the 50 patients evaluated did not meet the inclusion criteria and two of them did not want to participate in the study, the baseline evaluations of 45 patients were made. The patients who were randomly divided into 3-group of 15 people were included in their treatment programs. During the therapy, 1 patient from Group 2 could not complete the treatment caused by an emergency health problem. No allergic reaction was observed during treatment. Other patients continued their treatment regularly and came to follow-ups. The patients reported that they did not use any analgesic treatment (such as NSAID and paracetamol) during the follow-up.

Table 1 summarizes the demographic characteristics and intergroup baseline evaluation of the patients.

### *Assessment of primary outcome: VAS change*

No differences were found between the groups regarding the VAS baseline scores (Table 1). In the intra group analyzes, the significant change in VAS lasted until the 4-week follow up in Groups 1 and

2, while Group 3 was not observed after the end of the treatment (Table 2). Additionally, repeated-measures ANOVA didn't show a significant interaction between the time and the groups ( $F_{3,705} = 1.959$ ;  $p = .109$ ) (Figure 3).

#### *Assessment of secondary outcomes*

The HTI was found to be similar between the groups before the treatment, at the end of the treatment, and at the four-week follow-up ( $p > 0.05$ ). A decrease in HTI was observed in all 3-group at the 4-week follow-up after treatment. (Table 2).

Significant between group differences were found in FFI-total, FFI-pain and FFI-activity limitation at 4 weeks after treatment when ESWT plus low-dye KT and ESWT plus sham-taping and ESWT alone groups were compared (Table 2). Also, repeated-measures ANOVA showed a significant interaction between the time and three-group in the FFI-total ( $F_{3,919} = 2.607$ ;  $p = .043$ ) (Figure 4). In the intergroup evaluation, the significant decrease in FFI-total, FFI-pain, and FFI-disability in Group 1 and Group 2 were detected in all pairwise time comparisons ( $p > 0.05$ ) (Table 2).

## 286 Discussion

287 In this study, the effects of ESWT plus low-dye KT, ESWT plus sham-taping, and only ESWT  
288 treatment in patients with PF were investigated. Low-dye KT added to ESWT treatment in pain and  
289 foot functional assessment was superior to ESWT plus sham-taping and ESWT only treatments.  
290 Although no difference was observed on the VAS (primary outcome) and the HTI scores, the co-  
291 administration of low-dye KT and ESWT treatment improved foot disability and activity limitation  
292 compared with sham-taping; also decreased pain and improved activity limitation compared with  
293 ESWT alone. Sham-taping added to ESWT had no effect on patients. In this study, the most evident  
294 change between the groups after the treatment was observed in the FFI-total score.

295 Although there is no study where KT treatment has been added to ESWT in the literature, there are  
296 studies comparing ESWT and KT treatment for patients with PF <sup>2 17</sup>. In the study conducted by  
297 Ordahan et al <sup>2</sup>, the patients with PF were randomly divided into 2 groups. ESWT treatment was  
298 applied to the first group, and KT was given to the other group, and no difference was detected  
299 between the groups in the end-of-treatment evaluation <sup>2</sup>. The evaluations of the aforementioned study  
300 were made at the baseline and at the end of the treatment, and there was a relatively short follow-up  
301 period. In this study, the fact that ESWT plus low-dye KT treatment achieved more effective outcomes  
302 than ESWT at 4 weeks after the treatment ended shows that effectiveness of low-dye KT application  
303 when added to the ESWT treatment, which is an accepted therapy <sup>18-21</sup>. Frassanito et al. applied ESWT  
304 plus KT to one group and ESWT to the other group by dividing patients with calcific tendinopathy in  
305 the shoulder <sup>22</sup>. As a result of the current study, similar to our study, ESWT plus KT treatment was  
306 found to be more effective than ESWT alone in a 12-week follow-up <sup>22</sup>.

307 In a meta-analysis investigating eight different methods in PF treatment, ESWT has been found to be  
308 more effective in reducing pain and has been reported to be a more optimal treatment compared with  
309 ultrasound, NSAID, and injection treatments (e.g., corticosteroid, platelet-rich plasma, and dry-  
310 needling) <sup>20</sup>. An important reason for its preference is that it is non-invasive and well tolerated due to  
311 its low side effect profile <sup>23</sup>. Its effect on plantar fascia has contributed to close down the inflammation  
312 and regenerate tissues by increasing neovascularization by collagen remodeling and reducing pro-  
313 inflammatory profile and calcification through angiogenesis-related markers <sup>21 24</sup>. ESWT therapy was

approved by the American Food and Drug Administration in 2000 to treat PF<sup>23</sup>. In this study, in accordance with the literature, a decrease in pain and improvement in foot function scale were observed in all groups after ESWT.

The low-dye taping method makes a difference from other taping methods with a biomechanical approach<sup>3</sup>. It reverses the heel to lift the medial longitudinal arch of the foot, unlike other banding methods that place the tape directly on the medial longitudinal arch to support the arch<sup>3</sup>. Low-dye taping, also called anti-pronation banding<sup>3 13</sup>, wraps the heel to fix the axis of rotation of the subtalar joint, which then controls the flattening of the arch behind the foot segments and characterized by bands that loosen the plantar fascia<sup>25</sup>. With this method, the medial longitudinal arch height of the foot increases and pronation decreases<sup>2</sup>. By contrast, Chen et al. could not find the effect of low-dye KT on the tensile load on the plantar fascia in asymptomatic runners<sup>13</sup>. The most important reason for this can be explained by the robust biomechanical structure of the foot in asymptomatic runners. Therefore, considering the low-dye KT as a foreground for patients with PF with overpronation than for patients with neutral biomechanics would be useful. On the other hand, the fact that there was no significant difference in outcome measures such as VAS and HTI in low dye CT applied with ESWT, which was used as a highly effective treatment method in this study, may be due to the relatively short follow-up period. Probably, it would have been possible to detect the change due to banding in the period after the effectiveness of ESWT.

While other treatment methods such as iontophoresis, ultrasound and cryotherapy are effective in reducing pain, taping methods try to correct bad foot biomechanics<sup>3 19 26</sup>. The patient group who underwent low-dye KT was superior in terms of lower pain scores and higher foot functions even four weeks after the treatment compared with the other two groups. This result is compatible with publications stating that more than one treatment modality should be used in combination rather than a single therapy for the treatment of PF<sup>19</sup>. Hyland et al compared the low-dye taping, sham-taping, plantar fascia stretching, and control groups with a pre-and post-treatment interval of 1-week<sup>3</sup>. As a result of this study, similar to our study, calcaneal taping treatment was found to be more effective for the relief of heel pain than the sham-taping and control groups. They used the patient-specific functional scale (PSFS) to examine the foot function in the aforementioned study and could not find a

difference as a result of the study. The most important reason for this may be that there is no questionnaire for PSFS to provide a specific functional evaluation of the foot <sup>3</sup>. By contrast, the FFI used in our study was a questionnaire that specifically provides the functional evaluation of the foot, which may explain the significant differences of the test results found in the post-treatment follow-up <sup>15</sup>.

## **Study Limitations**

The study has several limitations that should be highlighted. First, the anatomic evaluations of the foot and goniometric measurements were not performed. Although anatomic evaluation was not performed, this change in foot is likely to cause chronic pain. However, in our study, those with chronic pain (pain for more than six months) were not included. Second, the plantar fascia not objectively evaluated. The radiographic images of all the patients were examined, and only those with calcaneal spurs were included in the study. However, as a result of the treatment, no radiographic evaluation was made again. Also, 4 weeks of follow-up can be considered as a relatively short period to decide on efficacy of the treatment. Contrarily, being the first randomized-controlled study investigating low-dye KT added to ESWT is the main study strength. The other strength of the current study is that it is one of the pioneer studies in the literature that uses KT in the low-dye taping method in PF. In future studies, investigating the superiority of different banding methods used in PF will be helpful.

## **Conclusions**

In plantar fasciitis, treatment with adjuvant low-dye KT and ESWT was found to be superior to adjuvant sham-taping and ESWT alone in improving foot disability and foot activity limitation in the next 4-week. However, when examined according to pain and heel sensitivity, no difference was observed between treatments. Although ESWT is an effective treatment in the treatment of PF, the use of combined treatments with taping, which is an easily applicable method for this patient population, will provide long-term relief. Future studies are needed to evaluate this more accurately.

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374 **Authors' contributions**

375 All authors read and approved the final version of the manuscript.

376 **Study conception and design:** YBO, TA

377 **Acquisition of data:** TA

378 **Analysis and interpretation of data:** YBO

379 **Drafting of manuscript:** YBO

380 **Critical revision:** YBO, TA

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470 **Table Legends**

471 **Table 1.** Basic characteristics of groups

472 **Table 2.** Intergroup and intragroup changes in outcome variables.

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474 **Figure Legends**

475 **Figure 1.** The application of low-dye kinesio taping and sham taping

476 **Figure 2.** Consort diagram of the study.

477 **Figure 3.** Time course of the VAS score for three groups

478 **Figure 4.** Time course of the FFI – total score for three groups

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