

# Clinical Efficacy of Application-linked Stretching Ball as A Digital Therapeutics in Plantar Fasciitis: A Single-Blind Randomized Controlled Study

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**INTRODUCTION:** Conservative methods, such as stretching exercises, are considered the mainstay of treatment for plantar fasciitis. Although digital therapeutics have been highlighted in behavioral healthcare, the clinical efficacy of digital therapeutics for the treatment of plantar fasciitis is not well understood. Thus, we aimed to evaluate the efficiency of application-linked stretching ball instruments that record the rolling time and force of patients compared with a traditional simple stretching ball.

**METHODS:** This prospective, randomized, single-blind, and placebo-controlled study was approved by the Institutional Review Board of our hospital. From July 2021 to December 2022, twenty volunteers were recruited from our hospital, and informed consent was obtained from all participants included in the study. They have experienced pain for > 6 months with minimal response to conservative treatment, including oral medication, heel cup, physical therapy, or stretching. After screening, the participants were divided into a simple massage ball group (group A, n=8) and an application-linked massage ball group (group B, n=6). Six patients were lost to follow-up and were excluded from the final analysis. The application-linked massage ball sends information regarding the massages, such as the frequency and force of the massage on the foot, to the application of the patient's smartphone (Fig. 1). All patients were instructed to use either a simple massage ball or an application-linked massage ball at least three times a day for more than 5 min per session. Additionally, patients in group B were instructed to download applications and run them on their mobile phones. When using the devices, all the patients were instructed to maintain a sitting position and roll stretching balls on their affected soles, including the insertion site of the plantar fascia. All clinical outcomes were evaluated at the beginning of the study and 1-, 2-, and 3 month follow-up. The primary outcome measure was the Manchester-Oxford Foot Questionnaire (MOXFQ) score. To analyze the association between the application-linked stretching ball and MOXFQ scores at each time point (initial state and at one, two, and three months), a generalized estimating equation (GEE) method was used.

**RESULTS SECTION:** At the beginning of the study, the initial MOXFQ score was not significantly different between the two groups ( $p = 0.948$ ). At each time point, the MOXFQ score of the whole population did not improve significantly compared to that of the initial state ( $p = 0.181$ ). GEE modeling demonstrated that there was no significant difference in the improvement of the MOXFQ score between groups A and B during follow-up ( $p = 0.818$ ). In addition, no group-by-time interactions were observed ( $p = 0.419$ ) (Fig. 2).

**DISCUSSION:** We postulated that a considerable number of cases, which could have spontaneously resolved, may progress to chronic intractable plantar fasciitis because patients did not follow the general rules of stretching exercises, especially from the perspective of exercise frequency and strength. Anecdotally, we found that patients who received a paper sheet on which they were supposed to record the amount of stretching exercises showed favorable clinical outcomes in our previous pilot study. Therefore, we decided to conduct this study using an application-linked ball instrument. However, the efficacy of an application-linked massage ball for the treatment of plantar fasciitis was not as definite as that of a traditional simple stretching ball in patients whose symptoms persisted for at least six months. From this, we can assume that patients referred to tertiary medical centers, such as our institution, who sustained their symptoms for at least 6 months, may need further modalities such as injection or surgical treatment. We believe that we should have applied our modality to other patients whose symptoms lasted for less than six months. In addition, our study has some limitations in that the study was performed with a small sample size, and some patients were lost to follow-up, as well as in a single-blinded manner.

**SIGNIFICANCE/CLINICAL RELEVANCE:** Digital therapeutics can fill the gap between unmonitored home-based curative exercises and clinicians' observations. From this perspective, we believe that application-linked stretching ball instruments could help in earlier recovery from plantar fasciitis if we select proper patients.

Fig. 1. Application-linked massage ball sends information regarding the massage, such as the frequency and the force of massage on the foot, to the application in the patient's smartphone.



Fig. 2. Comparison of Manchester-Oxford Foot Questionnaire (MOXFQ) score between groups during follow-up. Group A is a simple massage ball group and Group B is an application-linked massage ball group.

