■ **FOOT & ANKLE**

# Effectiveness and safety of arthroscopy combined with radial extracorporeal shockwave therapy for osteochondritis of the talus: a prospective, single-centre, randomized, double-blind study

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### Aims

Arthroscopic microfracture is a conventional form of treatment for patients with osteochondritis of the talus, involving an area of < 1.5 cm$^2$. However, some patients have persistent pain and limitation of movement in the early postoperative period. No studies have investigated the combined treatment of microfracture and shortwave treatment in these patients. The aim of this prospective single-centre, randomized, double-blind, placebo-controlled trial was to compare the outcome in patients treated with arthroscopic microfracture combined with radial extracorporeal shockwave therapy (rESWT) and arthroscopic microfracture alone, in patients with ostechondritis of the talus.

### Methods

Patients were randomly enrolled into two groups. At three weeks postoperatively, the rESWT group was given shockwave treatment, once every other day, for five treatments. In the control group the head of the device which delivered the treatment had no energy output. The two groups were evaluated before surgery and at six weeks and three, six and 12 months postoperatively. The primary outcome measure was the American Orthopaedic Foot and Ankle Society (AOFAS) Ankle-Hindfoot Scale. Secondary outcome measures included a visual analogue scale (VAS) score for pain and the area of bone marrow oedema of the talus as identified on sagittal fat suppression sequence MRI scans.

### Results

A total of 40 patients were enrolled and randomly divided into the two groups, with 20 in each. There was no statistically significant difference in the baseline characteristics of the groups. No complications, such as wound infection or neurovascular injury, were found during follow-up of 12 months. The mean AOFAS scores in the rESWT group were significantly higher than those in the control group at three, six, and 12 months postoperatively (p < 0.05). The mean VAS pain scores in the rESWT group were also significantly lower than those in the control group at these times (p < 0.05). The mean area of bone marrow oedema in the rESWT group was significantly smaller at six and 12 months than in the control group at these times (p < 0.05).

### Conclusion

Local shockwave therapy was safe and effective in patients with osteochondiritis of the talus who were treated with a combination of arthroscopic surgery and rESWT. Preliminary results showed that, compared with arthroscopic microfracture alone, those treated with arthroscopic microfracture combined with rESWT had better relief of pain at three months postoperatively and improved weightbearing and motor function of the ankle.

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## Introduction

Various forms of treatment have been developed for the management of patients with osteochondral lesions of the talus, from conservative treatment to arthroscopic debridement and microfracture, mosaicplasty, and allograft or autologous chondrocyte implantation.[1-5] For patients with mechanical symptoms after acute osteochondral lesions, or failed conservative treatment for three to six months, surgery should be performed. For lesions of < 15 mm in diameter or < 1.5 cm$^2$ in area, arthroscopic microfracture is commonly performed.[3,6-8] This stimulates the release of bone marrow mesenchymal stem cells (MSCs) from the subchondral bone to fill the defect and form fibrocartilage.[3,6] Several studies have reported good mid-term clinical results in most patients.[9-11] Early postoperative pain and abnormal MRI findings are, however, common, and the long-term outcomes are not known. New forms of treatment are thus needed to relieve pain and improve the motor function of the ankle.

Recent studies have shown that extracorporeal shockwave therapy (ESWT) can induce neovascularization and stimulate the growth factors related to angiogenesis and osteogenesis.[12,13] Good results have been reported when ESWT has been used in the management of delayed fracture healing, infectious nonunion, and osteochondral injuries.[14-16] Lyon et al[17] showed that ESWT accelerated the healing of early osteochondral lesions in rabbit models and improved the quality of cartilage and subchondral bone. Zhang et al[18] recently showed that the use of ESWT relieved pain and improved the function of the ankle in patients with residual pain after arthroscopic treatment of osteochondral lesions of the talus. Osteochondritis of the talus has been included as an indication for ESWT by the International Society for Medical Shockwave Treatment since March 2008.[19]

In this study, patients with osteochondritis of the talus underwent arthroscopic debridement and microfracture combined with radial extracorporeal shockwave therapy (rESWT) to treat pain, increase the local blood supply, and promote chondrogenesis. To our knowledge, there has been no randomized controlled study dealing with this issue. The hypothesis was that, compared with arthroscopic debridement and microfracture alone, the combined technique would reduce pain and improve the function of the ankle, without notable complications.

## Methods

A randomized, double-blind, single-centre, placebo-controlled trial was performed at the Centre of Joint Surgery of the Southwest Hospital, Army Military Medical University, Chongqing, China. Two groups of patients were treated with arthroscopy and microfracture before enrolment, after which one group was given rESWT with energy output, and the control group was given sham shockwave treatment with no energy output.

Patients with osteochondritis of the talus (Hepple stages I to III)[20] who were treated between 1 June 2017 and 31 May 2019 were considered. The inclusion criteria were: patients aged between 18 and 80 years, with symptoms for > three months and MRI scans showing Hepple stage I to III osteochondritis. The exclusion criteria were: patients of other ages; those with Hepple stage IV osteochondritis on MRI with large cysts, osteoarthritis, gout, local infection, abnormal coagulation, and abnormal lower limb alignment; a history of surgery or ESWT to the ankle; those who required surgical repair of ankle ligaments or to treat other local lesions; pregnancy, deaf-muteness, and mental disorders; and those who could not guarantee to attend for follow-up. Ethical approval for this prospective study was granted by the Ethics Committee of the Southwest Hospital, Third Military Medical University (Army Medical University), Chongqing, China (registration number KY2017-8). All patients gave written informed consent.

A total of 44 patients were assessed at presentation, and 40 fulfilled the inclusion criteria. They were randomly assigned to either the rESWT or the control group. No patient was lost to follow-up. The demographic and clinical characteristics of the patients were similar in the two groups (Table I).

Patients were randomized by a computer-generated process in a 1:1 ratio, by the opening of a sealed envelope. The rESWT or its sham was subsequently undertaken by a physiotherapist not involved in the further management of the patients. The sham treatment was performed exactly as the rESWT, with a device which was similar in design, shape, vibration, and sound, but without shockwaves.

The patients, the outcome assessors, the research workers collecting and analyzing the data, and the authors were all blinded to the allocation of treatment. The therapist providing the rESWT and sham rESWT was not blinded. The blinding would not be revealed until the results were analyzed.

The preferred method of anaesthesia was lumbar plexus or sciatic nerve block or a spinal epidural. Patients were placed in a supine position and a thigh tourniquet was applied on the affected side while keeping the hip and knee flexed. A noninvasive traction device was used. Routine anteromedial and anterolateral portals were used for arthroscopy of the ankle with a 2.7 mm arthroscope. Proliferative inflammatory synovium was removed, and the damaged cartilage was debrided down

**Table I.** Demographic and clinical characteristics by group (n = 40).

| Variable | rESWT | Control | p-value |
|---|---|---|---|
| Patients, n | 20 | 20 | |
| **Sex, n** | | | 0.752* |
| Male | 10 | 9 | |
| Female | 10 | 11 | |
| Mean age, yrs (SD) | 47.40 (11.87) | 46.70 (13.44) | 0.862† |
| Mean BMI, kg/m$^2$ (SD) | 26.18 (3.16) | 24.82 (3.21) | 0.072‡ |
| **Side, n (%)** | | | 0.342* |
| Left | 8 | 11 | |
| Right | 12 | 9 | |
| History of trauma, n (%) | 12 (60) | 12 (60) | 1.000* |
| Mean duration of symptoms, mths (SD) | 36.80 (37.80) | 23.60 (17.61) | 0.505‡ |
| Mean AOFAS score (SD) | 62.05 (6.85) | 62.00 (4.65) | 0.979† |
| Mean pain VAS (SD) | 6.10 (1.12) | 6.00 (1.08) | 0.775† |
| Mean BME area on MRI, mm$^2$ (SD) | 86.22 (13.53) | 85.66 (22.55) | 0.925† |

*Chi-squared test.
†Independent-samples *t*-test.
‡Mann-Whitney U test.
AOFAS, American Orthopaedic Foot & Ankle Society; BME, bone marrow oedema; rESWT, radial extracorporeal shockwave therapy; SD, standard deviation; VAS, visual analogue scale.
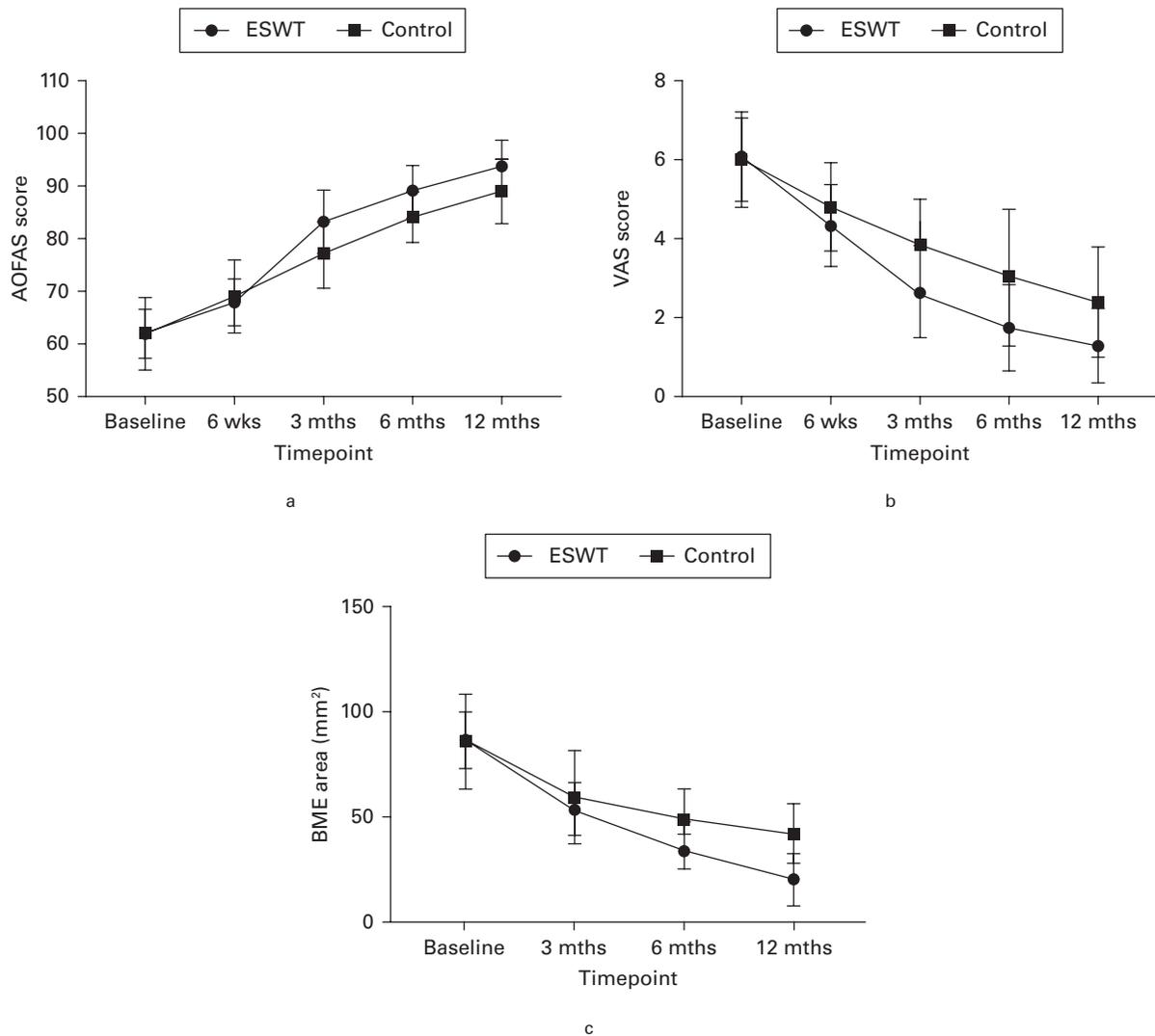
Fig. 1

Data of the two groups at baseline, six weeks, three, six, and 12 months. a) American Orthopaedic Foot and Ankle Society (AOFAS) scores. b) Visual analogue scale (VAS). c) The area of bone marrow oedema (BME) in the talus detected on sagittal fat suppression sequence MRI scans. ESWT, extracorporeal shockwave therapy.

to smooth stable articular cartilage. Routine microfracture was then undertaken,[21] with holes 3 to 4 mm apart with a depth of 2 to 4 mm. After releasing the tourniquet, marrow fat droplets and blood were seen to flow out of the holes. After routine wound closure, the ankle was immobilized in a short leg cast.

Three weeks postoperatively, those in the rESWT group were placed in a sitting or supine position, with the affected foot fixed on a stent or pillow. The positioning point of treatment was determined by the location of the osteochondritis on the MRI scans, the anatomical landmarks and the area of tenderness. The rESWT was administered using an EMS DolorClast and an EVO BLUE treatment head (both by Electro Medical Systems, Switzerland) with a diameter of 15 mm. The energy of the treatment was set to 1.5 to 2.0 bar, the energy flux density was between 0.02 and 0.05 mJ/mm² with a frequency of 6 Hz. Coupling gel was applied between the head of the treatment

device and the patient's skin to minimize the loss of shockwave energy, for better transmission of the wave. The therapist selected two or three treatment points for each treatment, each point receiving 1,000 impulses. Treatment was undertaken once every other day for five treatments.

Baseline data involved the demographic and clinical characteristics, including age, sex, height, weight, duration of symptoms, history of trauma, and the location of the osteochondritis. Standing anteroposterior and lateral radiographs of the ankle and MRI scans (0.2 T ARTOSCAN-C; ESAOTE, Italy) were obtained. The American Orthopaedic Foot and Ankle Association (AOFAS) Ankle-Hindfoot Scale and a visual analogue scale (VAS) score for pain were used to assess pain and function of the ankle.[22,23] The patients were reviewed regularly to record the complications. Assessments were recorded at baseline and at six weeks, and three, six, and 12 months, postoperatively.

**Table II.** Outcome measures in the two groups.

| Measure | ESWT mean (SD) | | | | | Control mean (SD) | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Baseline | 6 wks | 3 mths | 6 mths | 12 mths | Baseline | 6 wks | 3 mths | 6 mths | 12 mths |
| AOFAS score | 62.05 (6.85) | 67.95 (4.45) | 83.30 (5.96) | 89.10 (4.84) | 93.75 (4.89) | 62.00 (4.65) | 69.10 (6.89) | 77.20 (6.58) | 84.10 (4.76) | 89.05 (6.11) |
| VAS | 6.10 (1.12) | 4.35 (1.04) | 2.60 (1.10) | 1.75 (1.07) | 1.30 (0.92) | 6.00 (1.08) | 4.80 (1.11) | 3.85 (1.18) | 3.05 (1.73) | 2.40 (1.39) |
| BME area, mm$^2$ | 86.22 (13.53) | N/A | 53.33 (12.41) | 33.53 (8.36) | 19.96 (12.00) | 85.66 (22.55) | N/A | 59.06 (22.20) | 48.58 (14.64) | 41.86 (13.82) |

AOFAS, American Orthopaedic Foot & Ankle Society; BME, bone marrow oedema; ESWT, extracorporeal shockwave therapy; N/A, not applicable; SD, standard deviation; VAS, visual analogue scale.

The AOFAS and VAS pain scores were recorded at each time. Further MRI scans were performed at three, six, and 12 months to record the area of talar bone marrow oedema. The AOFAS and VAS pain scores were recorded by one examiner (CCZ). The MRI scans were assessed independently by two experienced radiologists (JC, CGZ). Minics software (Materialise, Belgium) was used to determine the largest area of talar bone marrow oedema in the sagittal fat suppression sequence. The recorded result was the mean of the value recorded by the two radiologists.

Intermittent ice compression was given within 72 hours after surgery with movement of the toes and straight leg raising. The cast was removed five days postoperatively when intermittent dorsi- and plantarflexion was commenced. At four weeks, the patient began to bear 10% of the body weight with an increase of 10% every day until reaching full weightbearing at eight weeks, when swimming, cycling, and other exercises could be undertaken.

**Statistical analysis.** On the basis of previous studies, an alternative hypothesis was that the AOFAS score would be ten points higher in the rESWT group compared with the control group.[24] The standard deviation (SD) of the AOFAS score was estimated to be ten points. We calculated that a sample of 16 in each group would be required to detect this difference, with a power of 90% and an α of 5%, with two-sided testing at a significance level of 0.05, assuming 10% loss to follow-up.

Continuous variables for all parameters were expressed as mean (SD) and variables were expressed as the number of patients (percentage) at each timepoint separately for the patients in the two groups. After determining, using the D'Agostino and Pearson omnibus normality test, whether the distribution of age, BMI, duration of symptoms, AOFAS and VAS pain score, and area of bone marrow oedema on MRI of the patients in both groups at baseline were consistent with a Gaussian distribution, baseline comparisons were performed with independent-samples *t*-tests, Mann-Whitney U tests, and chi-squared tests.

The development of mean AOFAS and VAS pain scores and the mean area of bone marrow oedema after treatment was investigated using a two-way repeated measures analysis of covariance (two-way RM ANCOVA), followed by parametric estimating for pairwise comparisons. Significance was set at p < 0.05. Calculations were performed using SPSS v. 25 (IBM, USA) and GraphPad Prism v. 8.2.1 (GraphPad, USA).

## Results

The mean AOFAS scores for the ESWT and control groups at baseline were 62.05 (SD 6.85) and 62.00 (SD 4.65), respectively, and improved in both groups during the study period to 93.75 (SD 4.89) and 89.05 (SD 6.11) (Figure 1a). The general linear model-repeated measurement (GLM-RM) procedure showed a significant effect for time (p < 0.001) and an interaction effect for treatment × time (p = 0.002). Parametric estimating showed statistically significant differences between the groups (Supplementary Table i).

The mean VAS pain scores for the rESWT and control groups were 6.10 (SD 1.12) and 6.00 (SD 1.08) at baseline, respectively, and decreased in both groups during the study period to 1.30 (SD 0.92) and 2.40 (SD 1.39) (Figure 1b).The GLM-RM procedure showed a significant effect for time (p < 0.001) and an interaction effect for treatment × time (p = 0.005). The parametric estimating showed statistically significant differences between the groups (Supplementary Table i).

The mean areas of bone marrow oedema are shown in Table II. These areas for the rESWT and control groups were 86.22 mm$^2$ (SD 13.53) and 85.66 mm$^2$ (SD 22.55) at baseline, respectively, and decreased in both groups over the study period to 19.96 mm$^2$ (SD 12.00) and 41.86 mm$^2$ (SD 13.82) (Figure 1c). The GLM-RM procedure showed a significant effect for time (p < 0.001) and an interaction effect for treatment × time (p < 0.001). Parametric estimating showed statistically significant differences between the groups at six and 12 months (p < 0.001) (Figure 2, Supplementary Table i).

Two patients (10%) in the ESWT group had a mild complication with transient reddening of the skin after a treatment, which disappeared within 24 hours. No serious adverse events were reported.

## Discussion

As far as we are aware, this is the first randomized double-blind controlled trial of arthroscopic microfracture combined with rESWT in the management of osteochondiritis of the talus that compared the results with sham rESWT. We found that the effect of rESWT after arthroscopic microfracture in these patients was significantly better than that after microfracture alone. There were no serious complications after 12 months. It is the first study to have also combined the results of subjective assessments (AOFAS and VAS pain scores) with objective radiological results (MRI).

The aim of the treatment of this condition is to create a stable environment for cartilage repair, to eliminate pain and restore function of the ankle. Many surgical procedures have been developed with the aim of producing long-lasting repair of the cartilage, but none is perfect. Microfracture is particularly used to treat small lesions, with an area of < 1.5 cm$^2$. It relies on pluripotent MSCs in bone marrow to fill cartilage defects and
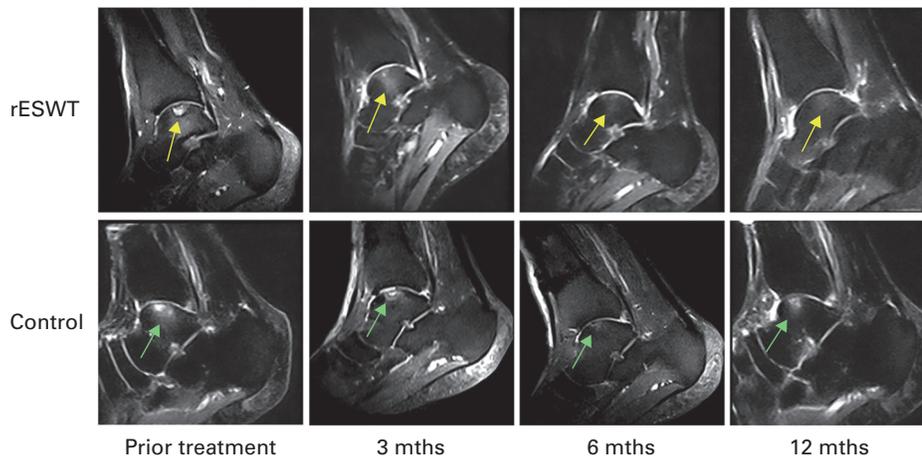
Fig. 2

MRI images showing the changes in bone marrow oedema in the rESWT and control groups. Yellow and green arrows indicate areas of bone marrow oedema.

form fibrin clots, which then form fibrocartilage repair tissue through redifferentiation.[21,25] Compared with untreated defects, microfracture has been shown to fill the defect with repair tissue, improve symptoms, and restore patients' athletic ability.[26,27] Many authors have shown that microfracture can achieve good early and mid-term results, and we have confirmed this.[27–30] However, a retrospective study showed that 15 of 78 patients (19.2%) who underwent arthroscopic microfracture for osteochondritis of the talus still complained of pain and restricted weightbearing three months after surgery,[18] suggesting that further treatment is needed to improve its efficacy.

Shockwave treatment has become a conventional part of the management of chronic pain in sports medicine. Compared with conventional focused EWST, rESWT has the greatest energy at its source. Its treatment is therefore more superficial, but can spread to treat larger areas than conventional ESWT,[31] which is more suited to the management of deep indications, such as avascular necrosis of the hip joint, whereas rESWT may be more suitable for superficial indications, such as osteochondritis of the talus.

The mechanism of action of the combined technology is still unclear and needs to be further explored. Potential mechanisms of action of rESWT in these patients include repeated mechanical stimulation of the area, microinjuries that stimulate bone remodelling, and some chondroprotective effects including reduction in the level of nitric oxide locally, chondrocyte apoptosis and increased vascular endothelial growth factor, bone morphogenetic protein-2, and osteocalcin in the subchondral bone.[32–39] A combination of these factors may produce a therapeutic effect in osteochondritis.

Ahn et al[40] showed that changes in the volume of bone marrow oedema after microfracture were correlated with the prognosis. Patients with new oedema or an increased volume of oedema postoperatively had worse outcomes. Transient oedema after bone marrow stimulation is considered a reactive response to the penetration of the subchondral bone by microfracture, but persistent oedema may be pathological after bone marrow

stimulation in osteochondritis.[41] Thus, we used the change in the area of marrow oedema as an indicator to observe. Current studies have confirmed that the defect after microfracture is mainly filled with fibrocartilage composed of type I collagen, not natural hyaline cartilage composed of type II collagen, which is structurally and biomechanically inferior.[42,43] We used low-resolution MRI instead of high-resolution MRI when measuring the area of bone marrow oedema, to reflect the efficacy of the repair of the injured cartilage. We found that most patients with osteochondritis of the talus showed significant improvement in this area 12 months after microfrcature combined with rESWT. This is consistent with recently reported results of shockwave therapy combined with retrograde autologous bone marrow cell transplantation for patients with osteochondritis of the talus;[24] and was also confirmed in a recent study of extracorporeal shockwave therapy for bone marrow oedema syndrome of the foot.[44]

There is currently no standard advice for early or delayed weightbearing after arthroscopic microfracture for osteochondritis of the talus. However, it was reported in a recent meta-analysis that good outcomes could be achieved with both early and delayed weightbearing after microfracture.[45] In our study, due to the addition of rESWT after surgery and the need for adequate rest during this, partial weightbearing was started from four weeks and full weightbearing at eight weeks after surgery and satisfactory outcomes were obtained. We therefore recommend this programme of postoperative weightbearing.

This study has limitations. So far, the mechanism of repair after rESWT has been insufficiently investigated. Although this was a prospective single-centre randomized double-blind placebo-controlled trial, the sample size was small and the follow-up was relatively short. However, it was originally designed as a short-term trial and patients who received other forms of treatment, such as analgesic medication or physiotherapy, were excluded. Therefore, we could not carry out long-term follow-ups, especially in the control group. We also chose the use of low-resolution rather than high-resolution MRI when

assessing the area of bone marrow oedema. In a future study, high-resolution MRI and Magnetic Resonance Observation of Cartilage Repair Tissue (MOCART)[46] scoring systems should be used to assess the repair of the damaged cartilage. However, the results of this study are encouraging. The sample size should be expanded in a multicentre study in the future to further verify our findings.

In summary, we found that, in patients who undergo arthroscopic microfracture osteochondritis of the talus, it was safe to perform local shockwave therapy after the wounds had healed. The combination of microfracture and shockwave therapy was more effective than microfracture alone, in the relief of pain, at three months postoperatively. This combination also resulted in improved weightbearing and motor function of the ankle.

### Take home message

- This study is the first randomized, placebo-controlled trial evaluating the effectiveness and safety of arthroscopy combined with radial extracorporeal shockwave therapy (rESWT) for osteochondral lesions of the talus.
- Compared with arthroscopy alone, arthroscopic microfracture combined with shockwave can better relieve local pain at three months after surgery, and improve the weightbearing and motor function of the ankle joint.
- Most patients showed significant improvement in the bone marrow oedema area on MRI scans at 12 months after arthroscopy combined with rESWT.

### Supplementary material

Table displaying the results of the statistical analysis.

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