# A comparative study of treatment interventions for patellar tendinopathy: a randomized controlled trial


## ABSTRACT

**Objective:** To determine the additional effect of dry needling (DN) or percutaneous needle electrolysis (PNE) combined with eccentric exercise (EE) and compare which one is the most effective for patients with patellar tendinopathy (PT).

**Design:** Blinded, randomized controlled trial, with follow-up at 10 and 22 weeks.

**Settings:** Recruitment was performed in sport clubs. The diagnosis and the intervention were carried out at San Jorge university.

**Participants**: Patients with PT with pain ≥3 months between 18 and 45 years.

**Interventions:** Three interventions were carried out: DN and EE group (DN-G), PNE and EE group (PNE-G) and EE with sham needle as the control group (CG).

**Main Outcome Measures:** Disability was measured with VISA-p. Visual Analogue Scale was used to measure pain overtime, Short Form-36 to measure quality of life and ultrasound to measure structural abnormalities.

**Results:** A total of 48 participants (42 men and 6 women, average age 32.46 (SD 7.14) years) were enrolled. The improvement in disability and pain in each group between baseline and post-treatment and baseline and follow-up was significant ($p \leq 0.05$), without differences among groups.

**Conclusion:** DN or PNE combined with an EE programme has not shown to be more effective than only an EE programme to improve disability and pain in patients with PT in the short (10 weeks) and medium (22 weeks) term. Clinical improvements were not associated with structural changes in the tendon.

**Keywords:** Patellar Tendinopathy; Tendinopathy; Percutaneous Needle Electrolysis; Dry Needling; Eccentric Exercise.

## LIST OF ABBREVIATIONS

CD-US=Colour Doppler ultrasound

CG=Control group

DN=Dry needling

DN-G=Dry needling intervention combined with eccentric exercise group

EE=Eccentric exercise

HSR=Heavy slow resistance training

PNE=Percutaneous needle electrolysis

PNE-G=Percutaneous needle electrolysis intervention combined with eccentric exercise group

PT=Patellar tendinopathy

QoL=Quality of life

RCT=Randomized controlled trial

SF-36=Short Form-36 Health Survey

VAS=Visual analogue scale

VISA-p=Victorian Institute of Sports Assessment Questionnaire, patellar tendon

Patellar tendinopathy (PT), also known as jumper´s knee, is a persistent patellar tendon pain at the inferior pole of the patella associated with loss of function related to mechanical loading(1). The overall prevalence in non-elite players from different sports is 8.5%(2), although this percentage increases in elite sports(3). Among elite volleyball and basketball players, the prevalence of jumper´s knee has been reported to be of 45% and 32%, respectively(3). In addition, PT is almost twice as common among male non-elite athletes when compared with female athletes(2). Moreover, it can negatively affects quality of life (QoL)(4).

The diagnosis is based on pain over the tendon with loading tasks and a loss of function. Although according to the ICON 2019 Statement(1, 5) structural changes were not identified as a core domain for PT diagnosis, Colour Doppler ultrasound (CD-US) images seem useful for obtaining quantitative information. Furthermore, quantitative analysis of echovariation has proven to be a useful tool for evaluation of musculoskeletal pathologies(6-8).

Eccentric exercise (EE) is considered the gold standard for conservative management and therefore accepted as the first-line approach for managing PT(9). Over the years, EE was shown to be effective in the treatment of various tendinopathies(10-12), including PT, and in this one there was greater clinical improvement when EE was performed on a declined surface(13). In the last years, some randomized controlled trials (RCTs) have investigated different types of exercise, such as heavy slow resistance training (HSR) or isometric, for the treatment of PT(14, 15), showing that both are effective at improving function and decreasing pain in the short and long term. Besides,

exercise has demonstrated to be superior than other conventional treatments, such as iontophoresis, US, Cyriax treatment, etc.(16, 17).

Other options have been proposed for health care practitioners that may be helpful for tendinopathy, such as dry needling (DN)(18, 19) and electrotherapeutic invasive modalities (e.g., percutaneous needle electrolysis (PNE))(20-23). Recently, research has focused on regenerative therapies because some of these techniques seem to achieve a faster improvement of the symptoms and a possible regeneration of the injured tendon(18, 21, 24). However, evidence-based regenerative therapies are limited, and there is no agreement to date regarding which of these therapies is the most effective(25).

Therefore, the aim of this study was to determine if the addition of either DN or PNE to EE was superior to sham needling and EE in patients with PT.

## MATERIAL AND METHODS

### Study design

A RCT with blinded assessors and participants was conducted to determine if the addition of either DN or PNE to EE was superior to sham needling and EE in patients with PT.

### Ethics

This RCT follows the standards of the Declaration of Helsinki and Good Clinical Practice and was approved by the Aragón Ethics Committee (Nº PI15/0017). The study was developed following the design of a previously published protocol(26).

## Participants

*Inclusion criteria*

Participants eligible for inclusion in this study met the following criteria: 1. Anterior knee pain located on the inferior pole of the patella for ≥3 months while practising sport; 2. Aged between 18 and 45 years; 3. Practicing any kind of sports at least 3 times a week; and 4. A score <80 on the Victorian Institute of Sport Assessment - Patellar questionnaire (VISA-p).

*Exclusion criteria*

Exclusion criteria for the study were: 1. Knee surgery within the previous 6 months; 2. Chronic joint diseases; 3. Corticosteroid injection in the patellar tendon within the previous 3 months; 4. Contraindications for needling (i.e., fear of needles, allergy to needle material); 5. Anti-inflammatory, analgesic or antibiotic medications within the previous 48 hours; and 6. Any other concomitant treatment for PT.

## Intervention

In the first session, all participants were instructed on how to perform three sets of 15 single leg squat repetitions on a decline board twice a day, according to Young's protocols(13), increasing the speed if participants did not have pain. Following the criteria found in studies carried out on the Achilles tendon(27), to achieve pain monitoring, the patients were informed that exercise was allowed to reach 5 in a numerical pain rating scale. It was not recorded whether patients were previously familiar with EE. The physiotherapist explained to all of them how to do the exercises to make sure that they knew how to do them at home.

For the needle intervention, the participants were placed in a supine position with a pillow under the knee (approximately 20º of knee flexion). The area was cleaned with an antiseptic solution (70% Propan-2-ol, Skin-des), and an US probe cover was used during the intervention. Each group received four sessions distributed throughout 8 weeks of treatment, once every 2 weeks. No participant had received any previous needling treatment in the tendon.

*DN intervention combined with EE group (DN-G) and PNE intervention combined with EE group (PNE-G)*

Specific DN needles were used during the needling treatments (Agu-punt, Spain). Considering the thickness of the tendon and the approach, 0.25 x 25 mm needles were used. The procedure was US-guided to ensure the specificity of application on the injured area and to guarantee that the procedure was safe for the patient. Each session consisted of three needle insertions lasting 3 seconds each. In the PNE-G applications, an intensity of 3 mA galvanic current was used during the 3 seconds that the procedure lasted.

*Control group (CG)*

A sham needle was placed upon the treatment zone, simulating the same procedure as the rest of participants enrolled in the other groups. Apart from the needle blinding with a sham needle, the physiotherapist performing the interventions placed high importance on the entire intervention experience, as cognitive influences that extend beyond mimicking of tactile sensations are recommended to create a believable simulation(28). The needle was placed in a specific holder and was manipulated during the intervention to simulate a real treatment.

## Outcomes

*Baseline data*

Baseline data included gender, age, height, weight, body mass index, affected side, level of physical activity performance, duration of symptoms, medication, previous rehabilitation treatments and any previous corticosteroid, PRP or drug injections. An assessor blind to treated evaluated all participants at baseline, as well as 10 weeks and 22 weeks after baseline.

*Primary outcome measure*

Disability was measured using the Spanish version of VISA-p(29). This questionnaire was designed to evaluate the severity of symptoms, knee function and ability to play sports in athletes with PT(30). The maximum VISA-p score for an asymptomatic athlete is 100 points. The VISA-p questionnaire has high reliability (ICC= 0.994; 95% CI: 0.992-0.996)(29).

*Secondary outcome measures*

The visual analogue scale (VAS)(31) was used to measure the level of pain overtime. Patients were asked about the mean and maximum pain that they had in the 24 hours prior to the assessment. The Short Form-36 Health Survey (SF-36) was used to assess QoL(32).

Ultrasonographic measures were made to assess tendon structure and was performed by the same person. US equipment (Logic S7 Expert, General Electric Healthcare) with a linear probe (MLG-15 5–10 MHz) was used. The ultrasonographic assessment protocol was carried out according to the Musculoskeletal US Technical

Guidelines, as defined by the European Society of Musculoskeletal Radiology(33). The presence of degenerative signs compatible with the medical diagnosis of PT (thickness of the tendon, hypoechoic areas, irregularities affecting the cortical bone and calcifications) that could be relevant for the selection of the target area were assessed. In addition, CD-US assessment was carried out to detect neovascularization.

The image analysis was performed by a different researcher blinded to the group with 20 years of experience in image analysis with high levels of reliability(34). ImageJ 1.52p software (National Institutes of Health, USA) was used to make a quantitative analysis of the CD-US image for the quantification of Doppler signals (Figure 1). Echointensity and echovariation were determined on a region of analysis (ROI) obtained in the longitudinal section. Three ROIs were selected, and the mean was used for statistical analysis.

**Sample size**

A calculation of statistical power was made prior to the study. Accepting an alpha risk of 0.05 and a beta risk of 0.80 in a bilateral contrast, 16 subjects are needed in every treatment group to detect a difference equal or superior to 15 points on the VISA-p and assuming a standard deviation of 15 points (35). The estimated loss to follow-up rate is 20%. For this reason, three more subjects are necessary in each of the groups, making a total of 19 subjects per group for this study.

**Recruitment**

Recruitment of subjects for the trial was carried out by means of informative campaigns targeted at different sports clubs and federations.

193

194 **Allocation**

195 Participants were randomly assigned by a researcher to the CG, DN-G or PNE-G
196 with a 1:1:1 allocation using an opaque envelope, with a block size of 15 participants.

197

198 **Blinding**

199 Assessments were made by an assessor blinded to treatment allocation. In order
200 to blind patients, all the interventions were made with the US and the PNE device
201 connected to simulate the same intervention in all groups. This procedure was designed
202 with the intention to blind the participants, but as this cannot guarantee complete blinding,
203 a questionnaire was administered at the end of the study. Patients were asked by email
204 ‘‘Do you know which treatment you received?’’ and the possible answers were: “No
205 needling treatment”, “Needling treatment” or “I don’t know”.

206

207 **Data management and statistical analysis**

208 The statistical analysis was performed with IBM SPSS Statistics (version 19,
209 IBM, Chicago, IL) and R version 3.6.1 jamovi package. The method for analysis was
210 intention to treat. Variables were described in number (percentage) and average (standard
211 deviation) or median (interquartile range) attending to their distribution. Baseline features
212 between groups were compared using one-way ANOVA for continuous data and the chi-
213 squared test for categorical data. Outcomes were analysed using mixed linear models
214 considering participants as a random effects and group of treatment as a fixed factor.
215 Pairwise Dunn-Bonferroni comparisons were performed as post hoc analyses. Finally, for
216 the determination of effect size of the group-by-time interaction, omega-squared ($\omega^2$) was
217 used. Intra-group effect size was determined by Hedges’ *h* (0.2 is considered a 'small'

effect size, 0.5 represents a 'medium' effect size and 0.8 represents a 'large' effect size). In addition, the percentage change from the baseline was calculated for clearer interpretation (Change%=(baseline-data/baseline)*100), so that positive values indicate an increase and negative values a decrease in the respective parameter.

Cohen's kappa coefficient was used to compute the agreement of group allocation between real allocation and the subject's guess. The significance level set for all the analyses was $p \leq 0.05$.

## RESULTS

A total of 72 patients were assessed for eligibility and finally 50 patients were recruited. Recruitment began in January 2019 and was completed in December 2019. Two participants dropped out of the study before starting the intervention. Finally, 48 non-elite players (42 men and 6 women, average age 32.46 (SD 7.14) years) were randomized into three groups. The flow chart of the trial is shown in Figure 2. No significant differences were found between the groups at baseline in terms of sociodemographic, clinical and ultrasonographic variables (Table 1 and 2) so none of them were introduced as a covariate in the linear model.

Eighteen patients didn't complete the blinded questionnaire after the last session, and two patients chose "Don't know". Therefore, data from 28 patients were used to calculate Cohen's kappa coefficient. Cohen's kappa coefficient was 0.14 (IC 95%, 0–0.30).

### Clinical outcomes

*Disability (VISA-p)*

There were no significant differences for the VISA-p score amongst the three groups. However, a significant effect was found in all groups at both the 10 and 22 weeks follow-ups ($p<0.01$). These results are shown in Table 3.

In addition, 66.67% of the patients obtained a clinically relevant improvement (more than 15 points in VISA-p) after receiving their treatment, achieved by almost 73% of patients in the medium term.

All the patients began the trial with less than 80 points in the VISA-p, and after eight weeks, the 39.6% of the patients reached a score higher than 80 points, which is considered normal for subjects without this pathology, which is considered as good function. This percentage increased to 54.17% at medium term.

*Pain over time (VAS)*

Mean VAS

There were no significant differences between groups for the VAS score mean. Regarding differences within groups, there were significant improvements at 10 weeks only for the PNE-G ($p=0.02$) and CG ($p=0.01$). At 22 weeks follow-up, there were significant improvements for all groups ($p\leq0.05$).

Maximum VAS

There were no significant differences for the maximum VAS score between groups. Regarding differences within groups, there were significant improvements in all groups at both the 10 and 22 weeks follow-ups ($p \leq0.05$).

*QoL (SF-36)*

There were no significant differences between groups for the SF-36 score. There were only significant improvements of QoL in the PNE-G ($p$=0.01) at 10 weeks follow-up, which was not maintained at 22 weeks follow-up.

*Tendon Structure (Ultrasonography)*

At baseline, the mean thickness of the patellar tendon of all the patients was 0.65 cm, improving over time to 0.61 at the end of the study. Furthermore, 43.75% of the patients presented neovascularization, decreasing to 31.25% at the end of the treatment. However, there were no statistically significant changes in these parameters along the time within groups. Also, there were no significant differences between groups in thickness, number of vessels, echointensity, echovariation, total area of vessels and mean area/vessel (Table 4).

## DISCUSSION

The results of this blind RCT indicate that treatment with DN and PNE combined with an EE protocol have not been shown to be more effective than an exercise programme to improve disability and pain in patients with PT in the short and medium term and that any of the treatments achieved structural changes.

In recent years, there have been reports of a beneficial effect of DN(19, 36-38) and PNE(20, 21, 39-42) in the treatment of tendinopathy but the results of comparative studies have not been reported. In the case of PNE, there are only two RCTs that have evaluated PNE versus other interventions. One study evaluated the effectiveness for adductor longus enthesopathy comparing PNE with a CG performing only the exercise

programme(43), whereas the other analysed the effect of PNE in plantar fasciosis compared with corticosteroid infiltration(41). These studies had similar sample and outcome measurements to ours, finding PNE was effective to improve pain and function but without differences between groups.

Regarding PNE in PT, only some observational descriptive studies have been published. Our study showed that all groups improved, which was similar to other studies utilizing the VISA-p(20, 21). Additionally, QoL showed a significant improvement at 10 weeks for the PNE-G only in the short term, which is similar to the study performed by Moreno et al.(43) that showed a trend in favour of PNE-G at the end of the treatment and 8 and 16 weeks later. However, this information should be treated with some caution because it was an isolated event. Only two studies have compared DN with other techniques, such as plasm-rich platelet (PRP)(19) and autologous blood(44), both combined with exercise protocols in all groups. However, none of them has been carried out with a CG to analyse if invasive techniques may have an additional effect compared with an exercise protocol alone. One of them(19) suggested that, at 26 weeks follow-up, DN improved functionality and pain, with better results than PRP. This suggests that there is no need to use PRP if minimally invasive techniques or exercise programmes can achieve better results in the short term.

In our study, we also analysed structural changes. We found that, despite the clinical improvements in all groups, there were no structural changes, at least at 3 months follow-up. This seems to agree with the current evidence supporting that there can be clinical changes despite not having structural improvements(1, 45-52). Besides, we also measured neovascularization, as some studies have suggested it is related to pain(53-55).

More studies are necessary to clarify the true cause of pain and the existence or not of a relationship between pain and tendon structure.

One of the biggest biases that we can usually find in clinical trials with needles is the true blinding of the patients. A systematic review reported that patient blinding was unsuccessful in 33% of trials(28). Evidence shows that inadequate blinding leads to exaggerated outcomes in clinical trials(56,57), and therapist behaviours, expectations about treatment protocols, visual aspects of the sham and clinical assessments could be important features of effective shams(58). There is still no agreement on the best method of blinding for this type of intervention, but in our study, we found that results obtained in the control and the DN group were not biased as participants had a good blinding and did not really know what intervention was being received. However, all the participants in the PNE group guessed the intervention they were allocated to. This insufficient blinding in the PNE group could have led to participants in this group to improve more as they were receiving one of the experimental treatments, although this did not occur.

*Study limitations*

The study enrolled a group of mostly men with a small number of women, which may entail that the findings are not generalizable to the latter group. Other limitation is related to the structural changes, as some studies indicate that structural changes may take a long time to appear, so future studies should consider structural assessments with longer follow-up to analyse if there are structural changes and if these changes are correlated with the clinical improvements. Although a sample size calculation was carried out based on similar studies, results should be interpreted with caution because in case that the study was underpowered, some treatment effects could have not been detected.

Our study, in contrast, is the first RCT evaluating two invasive techniques used in physiotherapy for PT with a CG and based on the gold standard treatment. Furthermore, we also analysed tendon structure and introduced an innovative analysis of both number and area of neovessels with US.

## CONCLUSION

DN or PNE combined with an EE programme has not shown to be more effective than only an EE programme to improve disability and pain in patients with PT in the short (10 weeks) and medium (22 weeks) term. Clinical improvements were not associated with structural changes in the tendon.


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535 **FIGURE LEGENDS**

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537 **Figure 1.** Doppler quantification.

538 Doppler ultrasound quantification by Image Analysis. The image was segmented, and the

539 number and size of Doppler signals were determined.

540

541 **Figure 2.** CONSORT flow diagram.