




# Ultrasound-guided percutaneous needle tenotomy (PNT) alone versus PNT plus platelet-rich plasma injection for the treatment of chronic tendinosis: A randomized controlled trial

Jonathan S. Kirschner MD<sup>1</sup>  | Jennifer Cheng PhD<sup>1</sup>  | Nicole Hurwitz BS<sup>1</sup> | Kristen Santiago BA<sup>1</sup>  | Emerald Lin MD<sup>1</sup> | Nicholas Beatty DO<sup>2,3</sup> | Dallas Kingsbury MD<sup>4</sup> | Ian Wendel DO<sup>5</sup> | Carlo Milani MD MBA<sup>1</sup>

<sup>1</sup>Department of Physiatry, Hospital for Special Surgery, New York, New York, USA

<sup>2</sup>Department of Rehabilitation Medicine, Mount Sinai Hospital, New York, New York, USA

<sup>3</sup>Regenerative SportsCare Institute, New York, New York, USA

<sup>4</sup>Department of Rehabilitation Medicine, NYU Langone Health, New York, New York, USA

<sup>5</sup>Tri-County Orthopedics, Cedar Knolls, New Jersey, USA

## Correspondence

Jonathan Kirschner, Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021, USA.

Email: kirschnerj@hss.edu

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## Abstract

**Background:** Tendinosis is a chronic degenerative condition. Current research suggests both percutaneous needle tenotomy (PNT) and leukocyte-rich platelet-rich plasma (LR-PRP) may be effective treatments for chronic tendinosis, but no studies have assessed the effectiveness of PNT alone versus PNT with intratendinous LR-PRP for multiple tendon types in a single study.

**Objective:** To assess the efficacy of PNT versus PNT + LR-PRP to treat chronic tendinosis.

**Study Design:** Double-blind, randomized, controlled comparative treatment study.

**Setting:** Primary academic institution.

**Participants:** A convenience sample of 40 participants who had chronic tendinosis (rotator cuff, wrist extensor, wrist flexor, hip abductor, proximal hamstring, patellar, or Achilles) confirmed via ultrasound, failed conservative treatment, and did not have tendon tears, known coagulopathy, or systemic illnesses.

**Interventions:** Participants were randomly assigned to PNT ( $n = 19$ ) or PNT + LR-PRP ( $n = 21$ ). Participants and outcomes assessors were blinded to treatment assignments. PNT was performed with 20–30 passes of a 22-gauge needle under ultrasound guidance, with 1% lidocaine given outside the tendon. LR-PRP was processed from whole blood (30–60 mL) and injected into the affected tendon using the same PNT technique.

**Main Outcome Measures:** Primary outcome was current numerical rating scale pain at 6 weeks. Secondary outcomes were average pain, function, general well-being, and sleep quality at 6, 52, and 104 weeks.

**Results:** Baseline characteristics were similar between groups. Overall, there were no significant differences between groups over time for any of the outcomes ( $P > .05$ ). Between-group analyses showed significantly lower current

and average pain after PNT compared to PNT + LR-PRP at 6 weeks (estimated-mean [SE]: 3.1[0.4] vs. 4.6[0.6],  $P = .04$ ; 3.4[0.4] vs. 4.9[0.5],  $P = .03$ ) only. Adverse event rates were low (PNT-3.9%; PNT + LR-PRP-5.0%) and related primarily to postprocedural pain and inflammation.

**Conclusions:** Although pain scores were lower after PNT compared to PNT + LR-PRP at 6 weeks, there were no between-group differences in outcomes at 52 or 104 weeks.

## INTRODUCTION

Symptomatic chronic tendinosis is characterized by micro- and macro-structural changes in tendon architecture. Histopathologic changes of chronic tendinosis include disorganization of collagen fibers, proliferation of irregular cell material, tendon fraying and microtears, and neovascularization.<sup>1</sup> Gross changes include tendon thickening, synovial sheath hypertrophy, and larger tendon tears.<sup>1</sup> Degenerative changes in chronic tendinosis often occur without histologic signs of inflammation and may indicate a failed healing response.<sup>2</sup>

The prevalence of tendinosis can vary by body location for different patient populations. For example, Achilles tendinosis affects only 6% of the sedentary population but approximately 50% of elite endurance athletes.<sup>3</sup> Gluteus medius tendinosis affects 24% of women but only 9% of men between the ages of 50 and 79 years.<sup>3-5</sup> Symptoms at the site of involvement may include tenderness, swelling, pain with loading, and impaired function.<sup>2,6</sup> Initial nonoperative treatment for chronic tendinosis may include observation, oral or topical medications, physical therapy, and therapeutic concentric and eccentric strengthening exercises.<sup>7,8</sup> Although chronic symptomatic tendinopathies typically respond to non-procedural treatments more favorably compared to surgical treatments,<sup>7</sup> symptoms may be recalcitrant. Historically, peritendinous corticosteroid injections have been a common intervention for recalcitrant tendinopathy, but recent evidence suggests corticosteroid injections may offer short-term pain relief at the cost of poor long-term outcomes.<sup>9</sup> For this reason, alternative treatments for tendon regeneration have been pursued, although the degree to which actual regeneration occurs with various treatments versus pain relief via mechanisms other than tissue regeneration is still heavily debated. Two regenerative treatments that have received increased interest include percutaneous needle tenotomy (PNT), which is also known as tendon fenestration or barbotage,<sup>10</sup> and intratendinous platelet-rich plasma (PRP) injection.<sup>11</sup>

Both PNT and PRP hold potential for the treatment of recalcitrant chronic tendinosis. PNT is thought to convert tendinosis from a chronic nonhealing state to an acute injury state with enhanced healing capability.<sup>12,13</sup> Enhanced healing is thought to occur through a local inflammatory response after repetitive needling of tendinotic tissue to disrupt the affected tendon fibers and induce bleeding.<sup>13</sup> Improvements in tendinosis-related

symptoms following ultrasound-guided PNT have been shown in several studies.<sup>13,14</sup> PRP is an emerging treatment in which participants' platelets, and the growth factors contained therein (eg, platelet-derived growth factor, vascular endothelial growth factor, epithelial growth factor), are centrifuged from whole blood and are used for intra- or peritendinous injection. The platelets in PRP are typically concentrated 3–8 times more than in whole blood, and this concentration may promote healing.<sup>15</sup> The regenerative potential for tendinosis with PRP is well established in both in vitro and in vivo animal models.<sup>16</sup> In humans, however, recent meta-analyses have shown conflicting results with regard to the effectiveness of PRP for different types of tendinopathy. Nauwelaers et al demonstrated no differences in clinical outcomes between PRP- and placebo-treated participants with chronic midsubstance Achilles tendinopathy.<sup>17</sup> In contrast, other meta-analyses have shown greater improvements with PRP treatment compared to control during long-term follow-ups.<sup>18-20</sup> It is suggested that the heterogeneity of outcomes may stem from the widely variable methods of PRP preparation and injection technique used among studies.<sup>21</sup>

In addition to its use as a standalone treatment, PRP can be administered as an adjuvant to PNT; this involves an increased number of steps related to the processing and injection of the PRP. To our knowledge, no single study has compared PNT alone to PNT plus leukocyte-rich PRP (PNT + LR-PRP) for the treatment of recalcitrant chronic tendinosis in the upper and lower limbs, although this has been investigated in studies of individual tendons.<sup>22,23</sup> The objective of this study was to compare these treatments over 104 weeks and to evaluate outcomes with regard to pain, function, general well-being, and sleep quality. Our hypothesis was that the addition of LR-PRP to PNT would further improve outcomes compared to PNT alone.

## METHODS

### Study design

This was a double-blind, randomized comparative treatment study approved by the institutional review boards of the institutions where it was conducted. Written informed consent was obtained from all participants before any research activities. This study was registered at ClinicalTrials.gov and was conducted in

accordance with Consolidated Standards of Reporting Trials (CONSORT) guidelines.<sup>24</sup> Recruitment began in October 2012.

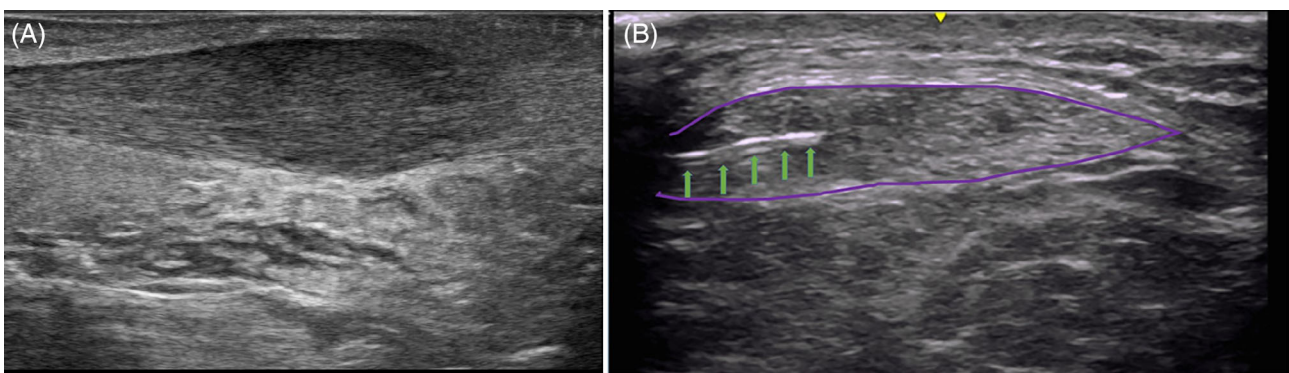
## Treatment allocation and administration

Inclusion criteria included age 18 to 100 years, findings consistent with chronic tendinosis confirmed clinically and with ultrasound, a numerical rating scale (NRS) pain score  $\geq 5$  out of 10, and  $\geq 3$  months of pain with failed initial treatment. Participants were excluded if they had partial or full thickness tears of the affected tendon, corticosteroid injection in the region of the affected tendon within the last 3 months, anticoagulant or antiplatelet medication use, known coagulopathy or bleeding dyscrasia, current or recent fluoroquinolone use, prior PNT or PRP injection to the affected tendon, other musculoskeletal injury or tendon rupture in the body region of interest, known systemic illness (eg, vasculitis, uncontrolled diabetes, autoimmune disease), involvement in workers' compensation or active litigation involving the affected tendon, or pregnancy. The absence of any tears in the affected tendon was confirmed on ultrasound. A representative image of tendinosis on ultrasound is shown in Figure 1A. Participants were asked to refrain from nonsteroidal anti-inflammatory drugs for a minimum of 5 days before starting treatment in the study. Following written informed consent, participants were randomly assigned (1:1) to receive PNT or PNT + LR-PRP; assignments were generated by nonclinical investigators using a computer-generated, block randomization scheme. Assignments were then placed in opaque envelopes corresponding to study identification numbers (#1–40). These envelopes remained unopened until informed consent was obtained. The participants and outcomes assessors were blinded to treatment group allocation, but the physician administering treatment was not blinded.

A single fellowship-trained, double board-certified, sports medicine physiatrist, who is also a registered musculoskeletal sonographer, performed all procedures in outpatient offices at two academic medical centers. Participants receiving PNT + LR-PRP had a standard upper limb blood draw to prepare the LR-PRP. To maintain blinding, participants receiving PNT alone underwent a sham blood draw and had a similar wait time to that of true PRP preparation, between the time of their blood draw and the time of their treatment. The syringe containing 1% lidocaine for the PNT group or PRP for the PNT + LR-PRP group was covered with opaque tape during treatment to ensure that the participant remained blinded to their treatment allocation. Both treatment groups received PNT with 20–30 passes of a 22-gauge needle under ultrasound guidance (Figure 1B: representative image of PNT on ultrasound). Both groups received local anesthesia subcutaneously with up to 3 mL of 1% lidocaine, taking care to use minimal lidocaine at the actual site of the tendon and no lidocaine in the tendon.

PRP was injected as the PNT was performed for the PNT + LR-PRP group to ensure the areas of maximal pathology were being targeted and to create intratendinous spaces for the PRP to be accepted, rather than the PRP being forced extratendinously or into the muscle belly. Any observed calcifications were disrupted in both groups.

The volumes of local anesthetic and LR-PRP injected were dependent on the size of the affected tendon (3–4 mL LR-PRP and 2 mL lidocaine for small tendons; 9–10 mL LR-PRP and 4 mL lidocaine for large tendons). The volume of whole blood drawn was 30 mL for small tendons (ie, common wrist flexor and extensor, rotator cuff [supraspinatus], patellar, Achilles, first dorsal compartment of the wrist) and 60 mL for large tendons (ie, gluteus medius, hamstring, quadriceps). LR-PRP was immediately processed from 30 to 60 mL whole blood using the Harvest SmartPrep Platelet Concentration System (Lakewood, CO), according to the



**FIGURE 1** Ultrasound images. (A) Representative image of Achilles tendinosis on ultrasound, long axis. Note the hypoechoic fusiform thickening. (B) Representative image of percutaneous needle tenotomy (PNT) of a patellar tendon using an in-plane, short-axis approach. The tendon is outlined in purple. Arrows identify the needle

manufacturer's instructions. LR-PRP was stored at room temperature before injections. No activating agent was added. The duration from blood draw to LR-PRP injection was less than 30 minutes.

Post procedure, participants were instructed to avoid icing the affected area for 3 days and to avoid nonsteroidal anti-inflammatory drugs for 8 weeks. Acetaminophen 500 mg or tramadol 50 mg were allowed for pain control. Participants were made non-weight-bearing guided by clinical recovery after lower limb procedures and told not to perform any carrying or lifting for upper limb procedures for 2–14 days to reduce risk of tendon rupture. Participants were given orthoses to immobilize the affected region for up to 14 days and allowed to wean based on their comfort. All participants underwent a structured rehabilitation protocol focused on the location of their tendinosis. Protocols included active range of motion and gentle stretching for postprocedure weeks 1–2, isometric exercises for weeks 2–4, concentric strengthening exercises for weeks 4–6, eccentric strengthening exercises for weeks 6–8, and plyometric and sports-specific exercise from the end of week 8 onward, when applicable. Participants could attend formal physical therapy, but it was not required. If participants elected to attend physical therapy, their therapist was made aware of the study rehabilitation protocol.

## Data collection and outcomes

Demographic data and questionnaires that assessed NRS pain, function, general well-being, and sleep quality on numerical rating scales of 0–10 were collected at baseline and postprocedure weeks 2, 4, 6, 8, 12, 24, 36, 52, and 104. An in-office evaluation was performed at week 4 by the treating attending physician. All other follow-ups were conducted by phone interview or online questionnaire, depending on the participant's preference. Each participant was evaluated for all outcome measures at each time point. The primary outcome measure for the study was current NRS pain score; a score of 0 indicated no pain, and a score of 10 indicated the worst pain imaginable. The primary outcome time point was 6 weeks. The minimal clinically important difference has been shown to be 2 points for NRS pain.<sup>25</sup> All other outcome measures were considered secondary outcomes. Average NRS pain score was assessed on the same numerical scale as current NRS pain. Function was assessed using the question, "How would you rate your function on average over the last week on the following numerical scale, where 0 means 'I functioned very well' and 10 means 'I could not function at all'?" Sleep quality was assessed using the question, "How would you rate your sleep on average over the last week on the following numerical scale, where 0 means 'I could not sleep at all' and 10 means 'I slept perfectly well'?" General well-being was assessed using the question, "How would you rate your general well-being

on average over the last week on the following numerical scale, where 0 means 'I am doing the worst ever' and 10 means 'I am doing very well'?" Secondary outcome time points were 52 and 104 weeks. Participants were also asked whether they would do the study treatment again as a measure of satisfaction ("Would you do the study treatment again?"). Data were collected and stored on Research Electronic Data Capture.

## Statistical analysis

This was a convenience sample of participants who met the eligibility criteria for the study. Continuous variables are reported as means and standard deviations (SDs) in the descriptive analysis. Frequencies and percentages are used to report descriptive statistics of discrete variables. Longitudinal analyses of outcome measures from baseline to 104 weeks were done using generalized estimating equation (GEE) modeling. GEE allows for the clustered analysis of all observations that have been collected longitudinally and accounts for any missing data from participants who were lost to follow-up. All observations were analyzed using maximum likelihood estimations. Models included time, group, and time\*group as predictors, with time treated as a continuous covariate. All parameter estimates from the GEE models are reported as means and SEs. Bonferroni correction was used to adjust for multiple pairwise comparisons at the primary and secondary outcome time points of 6, 52, and 104 weeks. All *P* values of the comparison of outcome scores at each time point between study arms are reported as the Bonferroni-corrected values. Therefore, statistical significance was defined as *P* < .05. All analyses were performed with SPSS, version 23.0 (IBM Corp., Armonk, NY).

## RESULTS

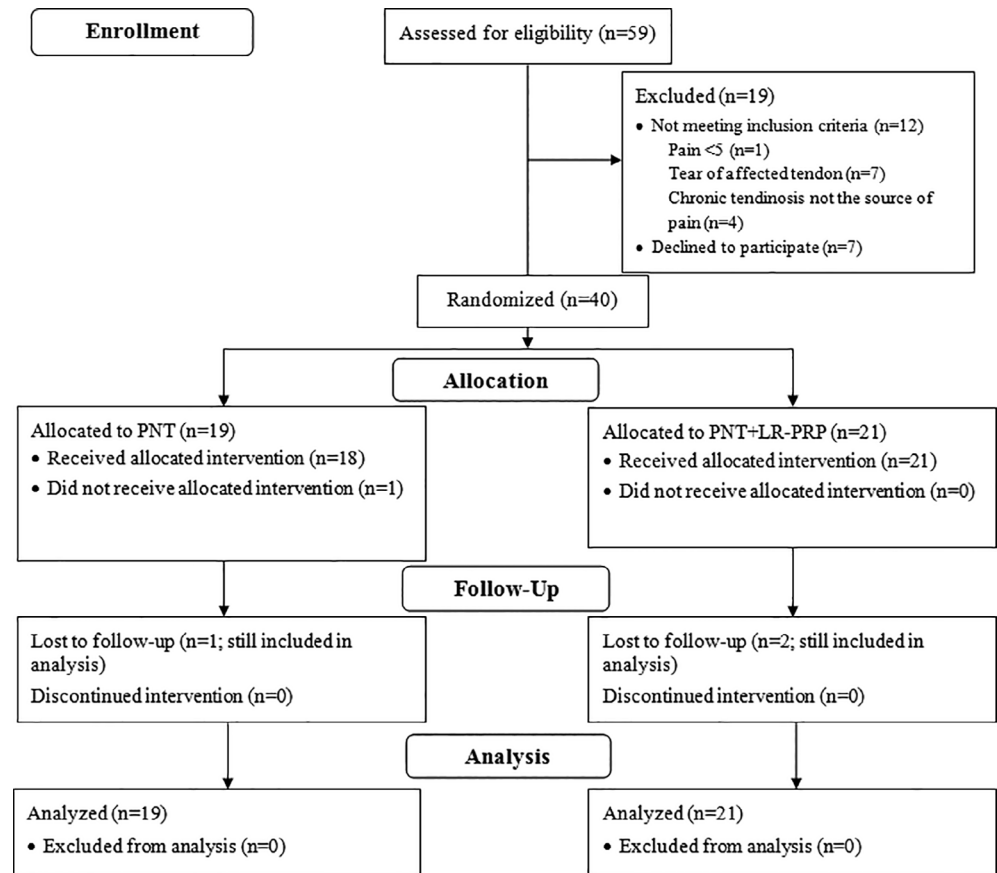
### Patient flow

Fifty-nine participants were assessed for eligibility from October 2012 to June 2017. Twelve participants did not meet inclusion/exclusion criteria, and seven participants declined to participate (Figure 2). A total of 40 participants with chronic tendinosis were enrolled and randomly assigned to receive PNT (*n* = 19) or PNT + LR-PRP (*n* = 21). The overall follow-up rate was 78% (data were collected for 281 out of 360 potential time points).

### Baseline group characteristics

Twenty-four male and 16 female participants were enrolled, with a mean age of 49 years. The mean duration of pain was 34 months. Baseline demographic data were not different between groups (Table 1). The most

**FIGURE 2** Consolidated Standards of Reporting Trials (CONSORT) flow diagram. The numbers of participants who were assessed for eligibility, excluded, enrolled, randomized, followed, and analyzed are shown. All enrolled participants were included in the intention-to-treat analysis, regardless of lost-to-follow-up status. LR-PRP, leukocyte-rich platelet-rich plasma; PNT, percutaneous needle tenotomy



common tendons affected were the common flexor and extensor tendons at the elbow (35%;  $n = 14$ ), followed by the gluteus medius (20%;  $n = 8$ ), the supraspinatus (18%;  $n = 7$ ), and the hamstring (15%;  $n = 6$ ). Twenty-two (55%) participants were actively involved in sports or exercise. All participants were nonsmokers. There were no significant differences in baseline pain scores, sleep quality, general well-being, or function between groups. In addition, there was no significant difference in distribution between upper and lower limb tendinopathies between groups.

## Outcomes

In each of the PNT and PNT + LR-PRP treatment groups, current and average pain scores decreased over time ( $P < .01$ ; Figure 3A, B). Overall, there were no significant differences between groups over time for current and average pain ( $P = .18$  and  $.29$ , respectively; Table 2). However, both current and average pain scores in the PNT group were significantly lower than those in the PNT + LR-PRP group at 6 weeks ( $P = .04$  and  $.03$ , respectively; Table 3). No differences between groups were observed at 52 or 104 weeks. The percentages of participants with clinically significant pain reductions at 6, 52, and 104 weeks are shown in

Table 4. When looking at upper and lower extremity tendinosis specifically, similar trends in current and average pain scores over time were observed (Supplemental Figures S1 and S2).

Function, general well-being, and sleep quality improved over time ( $P < .01$ ). However, there were no significant differences between groups over time in the overall model (Table 2). In addition, no between-group differences in function, general well-being, or sleep quality were observed at 6, 52, and 104 weeks (Table 3).

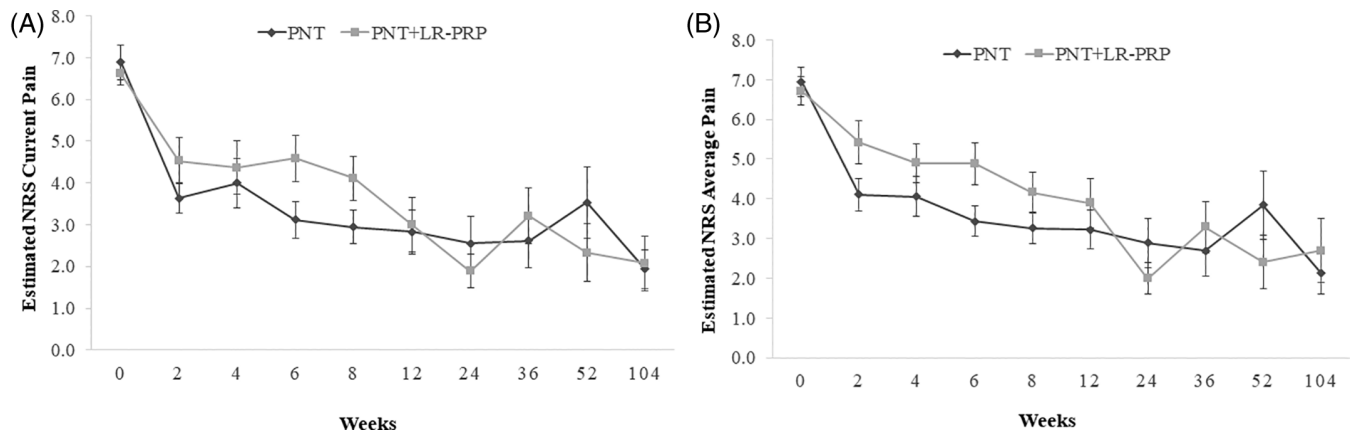
To assess satisfaction, participants were asked, "Would you do the study treatment again?" at the 104-week time point. In the PNT group, 12 participants responded "yes," three participants responded "no," and four participants did not answer the question. In the PNT + LR-PRP group, seven participants responded "yes," five participants responded "no," and nine participants did not answer the question. Thus, more participants in the PNT group stated that they would do the study treatment again; however, this difference was not statistically significant ( $P = .333$ ).

Adverse events were low overall, with rates of 3.9% and 5.0% in the PNT and PNT + LR-PRP groups, respectively. The most common adverse event reported was temporary muscle weakness around the affected joint. Other adverse effects included erythema and local edema. There were no serious adverse events.

**TABLE 1** Demographics and baseline information

	PNT (n = 19)	PNT + LR-PRP (n = 21)	P value
Age, years; mean (SD)	47.1 (15.5)	50.9 (15.3)	.44
Body mass index, kg/m <sup>2</sup> ; mean (SD)	26.3 (4.7)	24.5 (3.4)	.17
Males; n (%)	11 (57.9)	13 (61.9)	.80
Duration of symptoms, months; mean (SD)	25.4 (30.5)	43.5 (67.5)	.28
Tendon location; n (%)			.24
Elbow	6 (31.6)	8 (38.1)	
Wrist	0 (0.0)	1 (4.8)	
Shoulder	3 (15.8)	4 (19.0)	
Gluteus medius	6 (31.6)	2 (9.5)	
Knee	2 (10.5)	0 (0.0)	
Hamstring	2 (10.5)	4 (19.0)	
Achilles	0 (0.0)	2 (9.5)	
Lower extremity tendinopathy; n (%)	10 (52.6)	8 (38.1)	.36
Previous physical therapy; n (%)	10 (52.6)	12 (57.1)	.78
Current pain; mean (SD)	6.9 (1.9)	6.6 (1.3)	.56
Average pain; mean (SD)	6.9 (1.6)	6.7 (1.7)	.38

Abbreviations: LR-PRP, leukocyte-rich platelet-rich plasma; PNT, percutaneous needle tenotomy; SD, standard deviation.



**FIGURE 3** Estimated numerical rating scale (NRS) current and average pain. Estimated means and SEs for (A) NRS current pain and (B) NRS average pain from baseline (0 weeks) to 104 weeks are shown. Dark gray represents percutaneous needle tenotomy (PNT) group, and light gray represents PNT and leukocyte-rich platelet-rich plasma (PNT + LR-PRP) group

**TABLE 2** Results of model effects from interaction of time\*group

Outcome <sup>a</sup>	Beta <sup>b</sup>	SE	95% CI		P value
			Lower	Upper	
Current pain	-0.010	0.008	-0.025	0.005	.18
Average pain	-0.010	0.010	-0.029	0.009	.29
Function	-0.017	0.010	-0.036	0.002	.08
General well-being	0.001	0.006	-0.012	0.014	.89
Sleep quality	-0.004	0.008	-0.019	0.011	.61

Abbreviations: 95% CI, 95% confidence interval; SE, standard error.

<sup>a</sup>Current pain and average pain were on scales of 0–10, with 0 representing no pain and 10 representing worst pain imaginable. Function was on a scale of 0–10, with 0 representing best function and 10 representing no function. Sleep quality was on a scale of 0–10, with 0 representing no sleep (poor quality) and 10 representing best quality sleep. General well-being was on a scale of 0–10, with 0 representing worst well-being and 10 representing best well-being.

<sup>b</sup>Units are change in score per week.

**TABLE 3** Between-group comparisons of outcomes at 6, 52, and 104 weeks

Outcome	Weeks	PNT		PNT + LR-PRP		P value*
		M (SE)	N	M (SE)	N	
Current pain	0	6.9 (0.4)	19	6.6 (0.3)	21	.58
	6	3.1 (0.4)	16	4.6 (0.6)	17	.04
	52	3.5 (0.9)	13	2.3 (0.7)	15	.27
	104	1.9 (0.5)	15	2.1 (0.7)	13	.86
Average pain	0	6.9 (0.4)	19	6.7 (0.4)	21	.65
	6	3.4 (0.4)	16	4.9 (0.5)	17	.03
	52	3.8 (0.9)	13	2.4 (0.7)	15	.19
	104	2.1 (0.5)	15	2.7 (0.8)	13	.56
Function	0	6.5 (0.4)	19	6.2 (0.4)	21	.55
	6	4.1 (0.4)	16	4.5 (0.5)	17	.58
	52	2.8 (0.7)	13	2.4 (0.6)	15	.62
	104	3.5 (0.9)	15	2.3 (0.6)	13	.24
General well-being	0	5.6 (0.5)	19	6.2 (0.5)	21	.35
	6	7.5 (0.3)	16	6.8 (0.4)	17	.16
	52	7.9 (0.5)	13	7.2 (0.6)	15	.35
	104	8.1 (0.4)	15	8.2 (0.5)	13	.87
Sleep quality	0	5.0 (0.6)	19	6.3 (0.4)	21	.07
	6	7.0 (0.5)	16	6.8 (0.5)	17	.81
	52	7.7 (0.6)	13	7.1 (0.7)	15	.55
	104	7.2 (0.6)	15	6.8 (0.9)	13	.73

Abbreviations: LR-PRP, leukocyte-rich platelet-rich plasma; M, estimated mean; PNT, percutaneous needle tenotomy.

\*All *P* values have been adjusted using Bonferroni technique to account for potential Type I error due to multiple comparisons.

**TABLE 4** Clinically significant reductions in pain

	PNT	PNT + LR-PRP
Current pain		
6 weeks	14/16 (88)	10/17 (59)
52 weeks	8/13 (62)	13/15 (87)
104 weeks	14/15 (93)	12/13 (92)
Average pain		
6 weeks	12/16 (75)	10/17 (59)
52 weeks	8/13 (62)	12/15 (80)
104 weeks	15/15 (100)	11/13 (85)

Note: Results are number with clinically significant reductions in pain/total number available (percentage).

Abbreviations: LR-PRP, leukocyte-rich platelet-rich plasma; PNT, percutaneous needle tenotomy.

## DISCUSSION

In this double-blind, randomized, comparative treatment study, we assessed the effectiveness of PNT versus PNT + LR-PRP for chronic tendinosis in multiple tendon types. LR-PRP was prepared using a single system and was administered under ultrasound guidance. All treatments were performed by a single investigator with the goal to reduce larger variations in preparation and administration that might occur between multiple investigators.

Based on the findings of the current study, PRP appears to add limited value to needle tenotomy alone. These findings do not support the study hypothesis that the addition of LR-PRP to PNT will further improve outcomes compared to PNT alone for the treatment of symptomatic chronic tendinosis. One reason for this finding could be that stimulation of local growth factors from PNT alone, such as those signaled by pericytes (perivascular cells that may play a role in local tissue healing after injury) and platelets, is sufficient to stimulate a healing response in many cases.<sup>26</sup> It may be that increased concentration of growth factors from platelets in PRP does not add significant benefit over those local growth factors stimulated by PNT alone. Another possibility is that PRP may add value for treating certain grades of tendinosis (high vs. low grade), those with or without hyperemia, or those with partial thickness tears; however, this study was not designed to take those factors into consideration. Participants with partial thickness tears were specifically excluded from this study. Furthermore, PRP may be an effective addition to PNT for tendinosis in certain tendons but not others. This study was designed to evaluate all tendons together, however, and not to evaluate subclassifications of tendons. Further studies evaluating specific tendons are warranted.

Several other clinical studies investigating the role for PRP in chronic tendinosis have found no benefit of PRP over PNT or saline injections. De Jonge et al compared PRP to saline injections in the treatment of chronic midsubstance Achilles tendinopathy and found that both groups had improvements in Victorian Institute of Sports Assessment-Achilles scores at 1 year post treatment.<sup>27</sup> No between-group differences in clinical outcomes and tendon echotexture on ultrasound were found. Krogh et al reported similar findings in Victorian Institute of Sports Assessment-Achilles scores over a 3-month period, although they did find a significant increase in tendon thickness following PRP injections, compared to saline injections.<sup>28</sup> In the case of gluteus medius and gluteus minimus tendinopathy, Jacobsen et al compared a single-blind PRP injection with tendon fenestration in 30 participants and showed clinically significant improvements in pain scores in both groups; however, there were no differences between groups at a mean follow-up of 92 days. Additionally, Kesikburun et al found improvements in functional outcomes and visual analog pain scale at 1 year following PRP or saline injections for rotator cuff tendinopathy, but there were no differences between groups.<sup>29</sup> Similar findings were observed for elbow tendinopathy, with no differences in clinical outcomes following PNT with PRP compared to PNT with lidocaine.<sup>22</sup>

Conversely, several other clinical studies have suggested that PRP is effective and has a role in the treatment of specific tendinopathies. In a double-blind study, Rha et al compared PRP to dry needling in 39 participants with rotator cuff tendinopathy and found a clinically significant difference in the Shoulder Pain and Disability Index in favor of PRP at 2 weeks, 3, and 6 months. When pain scores and disability scores were analyzed independently, there were no significant differences, and there was also a high lost-to-follow-up rate in both groups (total cohort ~25%). In another double-blind trial, Dragoo et al compared the effects of PRP to dry needling in 23 participants with patellar tendinopathy.<sup>31</sup> The PRP group had clinically significant improvement compared to the dry needling group at 12 weeks but not at >26 weeks. PRP was concluded to accelerate recovery from tendinopathy initially, with dissipating effects over time.<sup>31</sup> Finally, a larger double-blind, multicenter trial of lateral epicondylitis conducted by Mishra and colleagues compared tendon needling with or without PRP.<sup>32</sup> Although no differences in participant-reported pain and tenderness at the lateral elbow were found between groups at 3 months, the PRP group had significantly greater improvement in visual analog pain scores and clinical tenderness at 24 weeks. The differences in findings between these studies and our study may be attributed to variations in PRP systems, concentrations, volumes, outcome measures, and/or injection technique. In addition, these variations likely

contribute to conflicting results in the overall literature on the efficacy of PRP treatment. Fitzpatrick et al performed a meta-analysis taking into account various studies' use of LR-PRP versus leukocyte-poor PRP (LP-PRP) in the treatment of chronic tendinopathy. The results suggested that LR-PRP is more effective than LP-PRP; however, most of the studies that were included in the meta-analysis used LR-PRP, and only one study used LP-PRP.<sup>21</sup>

## LIMITATIONS

This study was devised before current classification systems or reporting guidelines for biologic treatments were published, and cellular analyses (eg, platelet counts in PRP and whole blood) were not incorporated into the design.<sup>33,34</sup> Thus, we could not determine exact increases in platelet concentrations in the LR-PRP that was injected for each participant; however, previous studies have shown increases of 4.5–9-fold with the Harvest system.<sup>35,36</sup> Furthermore, 22% of overall follow-ups had missing data. To maximize all observations at all time points, we used GEE modeling, which allows for the clustered analysis of all observations that have been collected longitudinally. Additionally, not every participant underwent rigorous physical therapy prior to the study. Although this may have affected results, an initial multivariate regression analysis showed no effect of prior physical therapy on outcomes (data not shown). Furthermore, chronic tendinosis from various tendons were analyzed as a singular entity in this study. In particular, there was a higher number of participants with gluteus medius tendinosis in the PNT group compared to the PNT + LR-PRP group. Although no differences in treatment effect were found between treatment groups, further studies by tendon type may be warranted because of differential tendon loading and local tissue factors that influence tendon biology. Additionally, a validated measure was not used to assess functional outcomes; instead, participants were asked to rate their level of function on a subjective scale, and this was not specific to tendon type. Finally, as the sample size was small, the study may be underpowered. Therefore, larger sample sizes are needed in future studies to definitively confirm whether there are differences between PNT and PNT + LR-PRP treatments.

## CONCLUSION

At 6 weeks post treatment, current and average pain scores were significantly lower in the PNT group than in the PNT + LR-PRP group. However, no significant differences were observed between groups at 52 or 104 weeks post treatment. There were few adverse



effects noted with either treatment. For patients with chronic tendinopathy, PNT may be considered a viable treatment option in conjunction with a structured rehabilitation program, and the addition of PRP may provide no additional benefit. These findings may be of particular interest in planning treatment for chronic tendinosis when considering that PNT, but not PRP, is covered by most insurance carriers. For future studies, better classification and quantification of PRP and growth factors and standard reporting of other biologic samples are needed. The effect of tendon-specific factors should also be explored.


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## ORCID

Jonathan S. Kirschner  <https://orcid.org/0000-0002-9689-4090>

Jennifer Cheng  <https://orcid.org/0000-0001-8458-619X>

Kristen Santiago  <https://orcid.org/0000-0002-5813-2669>

## REFERENCES

- Xu Y, Murrell GA. The basic science of tendinopathy. *Clin Orthop Relat Res*. 2008;466(7):1528-1538.
- Kaux JF, Forthomme B, Goff CL, Crielaard JM, Croisier JL. Current opinions on tendinopathy. *J Sports Sci Med*. 2011;10(2):238-253.
- Scott A, Ashe MC. Common tendinopathies in the upper and lower extremities. *Curr Sports Med Rep*. 2006;5(5):233-241.
- Shiri R, Viikari-Juntura E, Varonen H, Heliövaara M. Prevalence and determinants of lateral and medial epicondylitis: a population study. *Am J Epidemiol*. 2006;164(11):1065-1074.
- Struijs PA, Kerkhoffs GM, Assendelft WJ, van Dijk CN. Conservative treatment of lateral epicondylitis: brace versus physical therapy or a combination of both—a randomized clinical trial. *Am J Sports Med*. 2004;32(2):462-469.
- Cook JL, Purdam CR. Is tendon pathology a continuum? A pathology model to explain the clinical presentation of load-induced tendinopathy. *Br J Sports Med*. 2009;43(6):409-416.
- Andres BM, Murrell GAC. Treatment of tendinopathy: what works, what does not, and what is on the horizon. *Clin Orthop Relat Res*. 2008;466(7):1539-1554.
- Rees JD, Maffulli N, Cook J. Management of tendinopathy. *Am J Sports Med*. 2009;37(9):1855-1867.
- Coombes BK, Bisset L, Vicenzino B. Efficacy and safety of corticosteroid injections and other injections for management of tendinopathy: a systematic review of randomised controlled trials. *Lancet*. 2010;376(9754):1751-1767.
- Chiavaras MM, Jacobson JA. Ultrasound-guided tendon fenestration. *Semin Musculoskelet Radiol*. 2013;17(1):85-90.
- Finnoff JT, Fowler SP, Lai JK, et al. Treatment of chronic tendinopathy with ultrasound-guided needle tenotomy and platelet-rich plasma injection. *PM R*. 2011;3(10):900-911.
- Jacobson JA, Kim SM, Brigido MK. Ultrasound-guided percutaneous tenotomy. *Semin Musculoskelet Radiol*. 2016;20(5):414-421.
- Housner JA, Jacobson JA, Misko R. Sonographically guided percutaneous needle tenotomy for the treatment of chronic tendinosis. *J Ultrasound Med*. 2009;28(9):1187-1192.
- McShane JM, Nazarian LN, Harwood MI. Sonographically guided percutaneous needle tenotomy for treatment of common extensor tendinosis in the elbow. *J Ultrasound Med*. 2006;25(10):1281-1289.
- Nguyen RT, Borg-Stein J, McInnis K. Applications of platelet-rich plasma in musculoskeletal and sports medicine: an evidence-based approach. *PM R*. 2011;3(3):226-250.
- Baksh N, Hannon CP, Murawski CD, Smyth NA, Kennedy JG. Platelet-rich plasma in tendon models: a systematic review of basic science literature. *Art Ther*. 2013;29(3):596-607.
- Nauwelaers AK, van Oost L, Peers K. Evidence for the use of PRP in chronic midsubstance Achilles tendinopathy: a systematic review with meta-analysis. *Foot Ankle Surg*. 2020;30163-30166.
- Chen X, Jones IA, Park C, Vangsness CT Jr. The efficacy of platelet-rich plasma on tendon and ligament healing: a systematic review and meta-analysis with bias assessment. *Am J Sports Med*. 2018;46(8):2020-2032.
- Lin MT, Wei KC, Wu CH. Effectiveness of platelet-rich plasma injection in rotator cuff tendinopathy: a systematic review and meta-analysis of randomized controlled trials. *Diagnostics*. 2020;10(4):189.
- Miller LE, Parrish WR, Roides B, Bhattacharyya S. Efficacy of platelet-rich plasma injections for symptomatic tendinopathy: systematic review and meta-analysis of randomised injection-controlled trials. *BMJ Open Sport Exerc Med*. 2017;3(1):e000237.
- Fitzpatrick J, Bulsara M, Zheng MH. The effectiveness of platelet-rich plasma in the treatment of tendinopathy: a meta-analysis of randomized controlled clinical trials. *Am J Sports Med*. 2017;45(1):226-233.
- Martin JI, Atilano L, Merino J, et al. Platelet-rich plasma versus lidocaine as tenotomy adjuvants in people with elbow epicondylitis: a randomized controlled trial. *J Orthop Surg Res*. 2019;14(1):109.
- Gaspar MP, Motto MA, Lewis S, et al. Platelet-rich plasma injection with percutaneous needling for recalcitrant lateral epicondylitis: comparison of Tenotomy and fenestration techniques. *Orthop J Sports Med*. 2017;5(12):2325967117742077.
- Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *Int J Surg*. 2012;10(1):28-55.
- Farrar JT, Young JP Jr, LaMoreaux L, Werth JL, Poole RM. Clinical importance of changes in chronic pain intensity measured on an 11-point numerical pain rating scale. *Pain*. 2001;94(2):149-158.
- Birbrair A, Zhang T, Wang ZM, Messi ML, Mintz A, Delbono O. Pericytes at the intersection between tissue regeneration and pathology. *Clin Sci*. 2015;128(2):81-93.
- de Jonge S, de Vos RJ, Weir A, et al. One-year follow-up of platelet-rich plasma treatment in chronic Achilles tendinopathy: a double-blind randomized placebo-controlled trial. *Am J Sports Med*. 2011;39(8):1623-1629.

28. Krogh TP, Ellingsen T, Christensen R, Jensen P, Fredberg U. Ultrasound-guided injection therapy of Achilles tendinopathy with platelet-rich plasma or saline: a randomized, blinded, placebo-controlled trial. *Am J Sports Med.* 2016;44(8):1990-1997.
29. Kesikburun S, Tan AK, Yilmaz B, Yasar E, Yazicioglu K. Platelet-rich plasma injections in the treatment of chronic rotator cuff tendinopathy: a randomized controlled trial with 1-year follow-up. *Am J Sports Med.* 2013;41(11):2609-2616.
30. Rha DW, Park GY, Kim YK, Kim MT, Lee SC. Comparison of the therapeutic effects of ultrasound-guided platelet-rich plasma injection and dry needling in rotator cuff disease: a randomized controlled trial. *Clin Rehabil.* 2013;27(2):113-122.
31. Dragoo JL, Wasterlain AS, Braun HJ, Nead KT. Platelet-rich plasma as a treatment for patellar tendinopathy: a double-blind, randomized controlled trial. *Am J Sports Med.* 2014;42(3):610-618.
32. Mishra AK, Skrepnik NV, Edwards SG, et al. Efficacy of platelet-rich plasma for chronic tennis elbow: a double-blind, prospective, multicenter, randomized controlled trial of 230 patients. *Am J Sports Med.* 2014;42(2):463-471.
33. Mautner K, Malanga GA, Smith J, et al. A call for a standard classification system for future biologic research: the rationale for new PRP nomenclature. *PM R.* 2015;7(4 Suppl):S53-s59.
34. Murray IR, Geeslin AG, Goudie EB, Petrigliano FA, LaPrade RF. Minimum information for studies evaluating biologics in Orthopaedics (MIBO): platelet-rich plasma and mesenchymal stem cells. *J Bone Joint Surg Am.* 2017;99(10):809-819.
35. Fitzpatrick J, Bulsara MK, McCrory PR, Richardson MD, Zheng MH. Analysis of platelet-rich plasma extraction: variations in platelet and blood components between 4 common commercial kits. *Orthop J Sports Med.* 2017;5(1):2325967116675272.
36. Le ADK, Enweze L, DeBaun MR, Dragoo JL. Current clinical recommendations for use of platelet-rich plasma. *Curr Rev Musculoskelet Med.* 2018;11(4):624-634.

## SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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## CME Question

This original research study showed that

- a) Both current and average pain scores were significantly lower in the Percutaneous Needle Tenotomy with Leukocyte-Rich Platelet-Rich Plasma (LR-PRP) treatment group than the Percutaneous Needle Tenotomy (PNT) alone treatment group at 52 weeks.
- b) Both current and average pain scores were significantly lower in the Percutaneous Needle Tenotomy with Leukocyte-Rich Platelet-Rich Plasma (LR-PRP) treatment group than the Percutaneous Needle Tenotomy (PNT) alone treatment group at 104 weeks.
- c) Both current and average pain scores were significantly lower in the Percutaneous Needle Tenotomy (PNT) alone treatment group than the Percutaneous Needle Tenotomy with Leukocyte-Rich Platelet-Rich Plasma (LR-PRP) treatment group at 6 weeks.
- d) Function, general well-being and sleep quality improved significantly greater in Percutaneous Needle Tenotomy (PNT) alone treatment group than the Percutaneous Needle Tenotomy with Leukocyte-Rich Platelet-Rich Plasma (LR-PRP) treatment group at 6 weeks.

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