Comparing the effects of positional versus myofascial release of gluteus medius to manage patellofemoral pain syndrome: single blinded randomized clinical trial

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Abstract

Objective: To determine the effects of positional release technique in comparison to myofascial release technique on gluteus medius trigger point along with exercises to manage patellofemoral pain syndrome.

Method: The single-blind, two-arm, randomised clinical trial was conducted at the Department of Physiotherapy, Sindh Institute of Physical Medicine, Karachi, from December 7, 2020, to March 24, 2021, and comprised patellofemoral pain syndrome of either gender with gluteus medius trigger point. They were randomly allocated to positional release technique group A and myofascial release technique group B. The intervention comprised 3 sessions per week for 6 weeks for a total of 18 sessions, with each session lasting 45 minutes. Function through anterior knee pain scale, pain through visual analogue scale, strength via hand-held dynamometer, and quality of life via World Health Organisation quality of life brief questionnaire were assessed alongside pressure pain threshold via algometer which was taken as the gluteus medius trigger point. All measurements were taken at baseline and 6 week post-intervention. Data was analysed using SPSS 21.

Results: Of the 64 participants, 38(59.4%) were females and 26(40.6%) were males. There were 32(50%) subjects in group A with mean age 29.50±5.84 years and 32(50%) in group B with mean age 29.50±5.43 years (p>0.05). Both the groups showed a significant reduction in pain, improvement in function, pressure pain threshold, strength, and quality of life (p<0.05). Intergroup comparisons revealed no significant differences (p>0.05).

Conclusion: Treating myofascial trigger points of gluteus medius muscle, using either positional release technique or myofascial release technique together with exercise therapy was found to be equally beneficial.

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Key Words: Anterior knee pain, Exercise therapy, Trigger points, Manual therapy.

Introduction

Patellofemoral pain syndrome (PFPS) is known to be an “orthopaedic enigma” having no definite diagnosis or treatment plan that could lead towards a successful outcome.1 It accounts for 25-40% of all knee problems and is mostly characterised by peripatellar, retropatellar or anterior knee pain which aggravates by activities imposing stress on the patellofemoral joint (PFJ), such as prolonged flexed knee sitting (a positive theatre sign), ascending and descending stairs, jumping, running or squatting. Global and local prevalence of PFPS in the general population is 23% and 19%, respectively, whereas the incidence accounts for 9.2%, with females 2-3 times more likely than males.2–4 The clinical diagnosis of PFPS is primarily based on exclusion. The association between PFPS and aetiological components are considered local (patellar alignment, its mechanics, and quadriceps strength), distal (mechanics of foot), and proximal (hip strength and its mechanics). These multifactorial aetiologies require multimodal moderate methodologies, including specific quadriceps exercises, patellar tapping and mobilisations, foot orthoses, and hip strengthening aimed at decreasing the compressive stresses on PFJ.5

Recent literature supports that altered hip biomechanics may lead to weak hip musculature that acts as an important contributing factor in PFPS, especially the gluteus medius (GMe) muscle. Being the primary hip abductor, it is the key muscle supporting the lower extremity during the mid-stance phase of gait, and is active throughout the gait cycle. It also maintains frontal plane alignment with the knee and foot.6 This muscle controls disproportionate valgus forces of the knee. The relationship between PFPS and changes in the eccentric
control increases internal rotation of the femur, escalating lateral contact pressure. Therefore, interventions for PFPS should focus on the significance of strengthening the hip musculature, to reduce excessive valgus stress on the knee.7

Excessive loading, weight-bearing and altered biomechanics of a muscle can lead to the development of myofascial trigger points (MTrPs), and researchers have found a strong correlation between GMe weakness and PFPS with increased prevalence of MTrPs in this muscle7.

The term myofascial trigger point was first coined by Travell and Simon who called it a “hyperirritable spot in a taut band of the skeletal muscle that is painful on compression, stretch, overload or contraction, and usually responds with a referred pain that is perceived as distant from the spot”. Although they distinguished many types of trigger points, namely, active, latent, satellite, primary and secondary, but only active and latent MTrPs are considered significant in clinical practice and research.9

An active MTrP has been defined as “a myofascial trigger point that causes a clinical complaint of pain. It is always tender, prevents full lengthening of the muscle, weakens the muscle, refers to a patient-recognised pain on direct compression, mediates a local twitch response when stimulated, and produces a referred motor phenomenon, often autonomic, in its reference zone when compressed within the patient’s pain tolerance, causing tenderness in the pain reference zone.” Comparably, a latent MTrP has been defined as “a myofascial trigger point that is clinically painless except when palpated. It may have all the clinical features of an active MTrP, including a taut band that increases muscle tension and limits the range of motion.”10

It is important to note when a tissue containing MTrPs is exercised before its deactivation, the referred pain is frequently stimulated or amplified. Therefore, as a general rule, MTrPs should be treated before strengthening or conditioning exercises to prevent its reactivation because when the tissue’s circulatory environment is improved and all the stress-producing biochemical and biomechanical origins are reduced or removed, the tissue’s normal function will return.11 The efficacy of trigger point therapy to manage PFPS has been a source of controversy along with a lack of consensus.12

From a clinical point of view, many interventions are geared towards eliminating the MTrPs, including the positional release technique (PRT) and the myofascial release technique (MFRT).

To our knowledge, no study has yet compared the effectiveness of PRT versus MFR in combination with hip and knee strengthening exercises in individuals with PFPS. The current study was planned to fill the gap by determining the effects of PRT in comparison to MFRT on GMe trigger point along with exercises to manage PFPS. It was hypothesised that PRT plus exercise therapy would be equally effective in comparison to MFRT plus exercise therapy.

**Materials and Methods**

The single-blind, two-arm, randomised clinical trial (RCT) was conducted at the Department of Physiotherapy, Sindh Institute of Physical Medicine, Karachi, from December 7, 2020, to March 24, 2021.

The study population included individuals with GMe MTrPs based on a specific criteria;13 spot tenderness, referred pain, local twitch response, and a jump sign on the affected lower limb, anterior knee pain for 1-3 months, pain during ascending and descending stairs, running or sports activity, squatting and prolonged sitting with age group 18-40 years and both genders. Participants with patellar dislocation, damaged cartilage and ligament of knee joint, soft tissue injury of knee, knee or hip surgery, lumbar spine dysfunction, sacroiliac joint dysfunction, pelvic mal-alignment, flat foot, chondromalacia patellae and young-onset osteoarthritis were excluded.

The sample was raised using non-probability, purposive sampling technique. The sample size was estimated using OpenEpi online calculator keeping PFPS prevalence at 27.6%14 with 95% confidence interval (CI).

Data was collected after taking approval from the institutional ethics review board of Dow University of Health Sciences (DUHS), Karachi.

The participants were screened by a physiatrist based on inclusion and exclusion criteria. They were then assessed for the presence of MTrPs of GMe in the affected lower limb. If present, informed consent was obtained and the principal investigator randomly assigned them into PRT plus strengthening exercise group A and MFRT plus strengthening exercise group B using a computer-generated randomisation software. The intervention comprised 3 sessions per week for 6 weeks for a total of 18 sessions, with each session lasting 45 minutes. Data was collected using Visual Analogue Scale (VAS)15, Anterior Knee Pain Scale (AKPS)15, algometer, hand-held dynamometer (HHD) and the World Health Organisation Quality of Life questionnaire’s brief version (WHOQOL-BREF).16 All measurements were taken at the baseline and 5 minutes after the last session 6 weeks later. The
procedure for assessing the outcome took 15 minutes. The CONSORT flow diagram is also given (Figure 1).

The outcome assessor was blinded to group randomisation.

The testing began by palpating the MTrPs. In a side-lying position with a pillow between the knees and hip in a neutral position, the GMe muscle was located at the posterior iliac crest with deep palpation. By applying resistive abduction, the density of GMe fibers was enhanced. The location of MTrPs were then noted at 3 potential locations. The first trigger point was immediately below the iliac crest and proximal to the greater trochanter. The second trigger point was found deep to the iliac crest, slightly anterior to the first trigger point. The last trigger point was found posterior to the tensor fascia latae muscle. The participants were scored as having at least 1 of the 3 MTrPs. Once located, the pressure pain threshold (PPT) was measured using an algometer which was positioned at 900 angle over the skin underlying the MTrPs. The participants were then instructed to describe any pain they experienced as soon as they were felt it. The trials were measured twice with a 30-second interval. Mean PPT value was calculated.

The participants were then assessed for hip abduction strength using a method described in literature. A pillow was positioned in between the knees of the participants in a side-lying position with the hip of the testing leg at approximately 100. The HHD (MicroFET2) was positioned 5cm proximal from the lateral knee joint line. The participants were instructed to push their thigh upwards with maximum effort for 5 seconds. After one practice trial, three experimental trials were performed with 15-second intervals. Maximum abduction strength was calculated using the peak output of the three trials.

Group A participants were subjected to PRT. The treatment started in a prone lying position with knees flexed. After palpating the MTrPs in the GMe muscle, a submaximal pressure of 1kg (2.2 lbs) or enough pressure to cause slight dimpling of the skin with the pads of your finger was maintained throughout the PRT treatment. The therapist moved the flexed knee into extension coupled with abduction by grasping the lower leg. Once the combination of abduction and extension was obtained, the hip was externally rotated. After the optimal treatment position was achieved, the therapist placed the patient’s thigh on his/her thigh. This position was held for 90 seconds, twice for 6 sessions. After the release, the hip was brought back into a neutral position slowly and passively.

Group B participants were subjected to MFRT. The treatment started in side-lying position, with the therapist standing behind them at the level of waistline and face front. After palpation of the MTrPs, the therapist used the knuckle of one hand to sink in the muscle overlying the MTrPs until the barrier to more depth was encountered. Slow and gentle pressure was applied. When there was a sustained change in the tone, a line of tension was added.

Positional Release Therapy

- Therapeutic Ultrasound 0.5 w/cm2, 3 mins on anterior knee
- Cold packs on the anterior knee for 3 minutes
- Knee strengthening exercises.
- Hamstrings (spine-lying) 3 sets x 10 repetitions, 10-second hold
- Plantar flexors (supine-lying) 3 sets x 10 repetitions, 10-second hold
- Quadriceps (sitting) 3 sets x 10 repetitions, 10-second hold
- Iliotibial band (standing) 3 sets x 10 repetitions, 10-second hold
- Hip strengthening exercises.
- Clam exercises with TheraBand (side-lying), 3 sets x 10 repetitions, 10-second hold
- Side stepping with TheraBand (standing), 3 sets x 10 repetitions, 10-second hold
- Unilateral bridge (supine), 3 sets x 10 repetition, 10-second hold
- Hip abduction with TheraBand (standing), 3 sets x 10 repetitions, 10-second hold
- Hip external rotation with TheraBand (sitting), 3 sets x 10 repetitions, 10-second hold
- Hip extension (quadruped position), 3 sets x 10 repetitions, 10-second hold.

Figure 2: Exercise regimes in addition to the interventions.
and the knuckle was moved in an inferior direction slowly. This movement across the surface was at least 2-3 cm, and was kept for 5-10 minutes for 6 sessions.18

Both groups received a therapeutic ultrasound at 0.5w/cm² and cold pack for 3 minutes on the anterior knee.

Also, both groups were taught strengthening exercises for the hip and knee musculature. For each exercise, the participants were instructed to execute 10 repetitions with a 10-second hold thrice a day, every day. When the trigger point was resolved, PRT and MFRT interventions were stopped and only a therapeutic ultrasound plus cold pack was given on the anterior knee, and they were told to continue the exercise protocol till the 6th week. On non-intervention days, the participants were instructed to perform exercises at home and were asked to mark the day on the patient’s exercise record sheet. The participants were also given a handout regarding the illustration of all the exercises. Thera Bands were provided to the participants for performing exercises at home (Figure 1).

The primary variables were self-reported distressing to unbearable pain measured by VAS. The participants were instructed to put a mark along the 10cm line indicating how much pain they were experiencing. The self-reported physical function was measured by AKPS, which is a 13-item questionnaire regarding knee function. The score of 100 indicated no disability and an increase in the score indicated improvement in the functions. PPT was measured using an algometer to assess the sensitivity of MTRPs. A lower value indicated a low pain threshold.

The secondary variables were muscle strength and quality of life (QOL). The strength of the GMe muscle was assessed using HHD in hip abduction. A lower value on the HHD indicated muscle weakness. QOL was assessed using the self-reporting WHOQOL-BREF questionnaire. A lower score indicated low QOL.

No harm or adverse events were reported during the trial.

Data was analysed using SPSS 21. Qualitative variables were presented as frequencies and percentages. Mean ± standard deviation (SD) were used for quantitative variables. Chi-square test was applied to investigate the association of the demographic variables except for age between the groups at baseline. Shapiro Wilk’s test was used to confirm data normality. Paired sample t-test and independent sample t-test were used to compare baseline and post-intervention values on each outcome within and between the groups. P <0.05 was considered statistically significant.

### Results

Of the 80 individuals assessed, 64(80%) were included (Figure 2); 38(59.4%) females and 26(40.6%) males. There were 32(50%) subjects in group A with mean age 29.50±5.84 years and 32(50%) in group B with mean age 29.50±5.43 years. At baseline, the groups showed no significant difference in terms of age, gender, marital status, affected knee, and duration of symptoms (Table 1).

#### Table-1: Baseline comparisons of the study groups.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Groups</th>
<th>PRT</th>
<th>MFR</th>
<th>Independent sample t-test</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td></td>
<td>29.50</td>
<td>29.50</td>
<td></td>
<td>1.000</td>
</tr>
<tr>
<td>Characteristics</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>P-value</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>12</td>
<td>37.5%</td>
<td>14</td>
<td>43.7%</td>
<td>0.799</td>
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<tr>
<td>Female</td>
<td>20</td>
<td>62.5%</td>
<td>18</td>
<td>56.2%</td>
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<tr>
<td>Marital status</td>
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<td></td>
<td></td>
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<tr>
<td>Single</td>
<td>15</td>
<td>46.8%</td>
<td>18</td>
<td>56.2%</td>
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<td>Married</td>
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<td>53.1%</td>
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<td>Affected knee</td>
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<td>Right</td>
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<td>59.3%</td>
<td>14</td>
<td>43.7%</td>
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<tr>
<td>Left</td>
<td>13</td>
<td>40.6%</td>
<td>18</td>
<td>56.2%</td>
<td></td>
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<tr>
<td>Durations of symptoms</td>
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<td>1 month</td>
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<td>6.2%</td>
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<td>1.5 months</td>
<td>10</td>
<td>31.2%</td>
<td>5</td>
<td>15.6%</td>
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<tr>
<td>2 months</td>
<td>14</td>
<td>43.7%</td>
<td>20</td>
<td>62.5%</td>
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<tr>
<td>2.5 months</td>
<td>8</td>
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<td>3 months</td>
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</tbody>
</table>

PRT: Positional release technique, MFR: Myofascial release technique, SD: Standard deviation.

#### Table-2: Within group comparison at baseline and 6th week scores

<table>
<thead>
<tr>
<th>Study Groups</th>
<th>Outcome Measures</th>
<th>Mean</th>
<th>Mean Difference</th>
<th>Standard Deviation</th>
<th>P-value</th>
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</thead>
<tbody>
<tr>
<td>PRT</td>
<td>AKPS Baseline</td>
<td>53.13</td>
<td>-41.20</td>
<td>11.59</td>
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<tr>
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<td>AKPS 6th Week</td>
<td>94.33</td>
<td>4.59</td>
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<td></td>
<td>Visual Analogue Scale Baseline</td>
<td>5.46</td>
<td>5.26</td>
<td>0.57</td>
<td>0.001</td>
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<td></td>
<td>Visual Analogue Scale 6th Week</td>
<td>0.20</td>
<td>0.48</td>
<td></td>
<td></td>
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<td></td>
<td>Algometer Baseline</td>
<td>2.77</td>
<td>-3.48</td>
<td>0.55</td>
<td>0.001</td>
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<td>Algometer 6th Week</td>
<td>6.26</td>
<td>1.44</td>
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<td>Hand-held dynamometer baseline</td>
<td>7.26</td>
<td>-4.95</td>
<td>1.38</td>
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<td>Hand-held Dynamometer 6th Week</td>
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<td>Quality Of Life (QOL)</td>
<td>Physical Baseline</td>
<td>22.38</td>
<td>-59.04</td>
<td>7.95</td>
<td>0.001</td>
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<td>Physical 6th week</td>
<td>81.42</td>
<td>7.86</td>
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<td></td>
<td>Psychological Baseline</td>
<td>30.63</td>
<td>-49.72</td>
<td>9.12</td>
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<td>Psychological 6th week</td>
<td>80.55</td>
<td>6.68</td>
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<td></td>
<td>Social Relations Baseline</td>
<td>53.61</td>
<td>-5.27</td>
<td>5.21</td>
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<td>Social Relations 6th week</td>
<td>58.88</td>
<td>9.77</td>
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<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>PRT</th>
<th>MFR</th>
<th>P-value</th>
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<tbody>
<tr>
<td>Hand-held Dynamometer (HHD)</td>
<td>12.22</td>
<td>12.03</td>
<td>0.71</td>
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<td>Algometer</td>
<td>6.26</td>
<td>5.97</td>
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<tr>
<td>Visual Analogue Scale (VAS)</td>
<td>0.20</td>
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<td>0.23</td>
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<tr>
<td>Anterior knee pain scale (AKPS)</td>
<td>94.33</td>
<td>94.40</td>
<td>0.95</td>
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<tr>
<td>Quality of Life (QoL)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Physical</td>
<td>81.43</td>
<td>82.86</td>
<td>0.41</td>
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<tr>
<td>Psychological</td>
<td>80.56</td>
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<tr>
<td>Social</td>
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<td>Environmental</td>
<td>70.94</td>
<td>72.29</td>
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</table>

*p<0.05 was considered statistically significant using an independent sample test
PRT: Positional release technique, MFR: Myofascial release technique, AKPS: Anterior knee pain scale.

Intergroup comparison showed no significant differences between the groups (p>0.05) (Table 3).

### Discussion

To our knowledge, the current research was the first rigorous study to appraise the combined efficacy of manual therapy along with exercise therapy to evaluate the effectiveness of PRT in comparison to MFR on the

MTrPs of GMe muscle combined with exercise therapy in the management of patients with PFPS.

The literature regarding MTrPs of GMe to manage PFPS is quite scarce. Only a few studies have been conducted and they identified a high prevalence of MTrPs of GMe muscle, with one study demonstrating these MTrPs to be latent, while another showing them to be active. Interestingly, in the current study, the participants had only one trigger point either active or latent, irrespective of its location in the affected limb. Recent studies demonstrated that MTrPs of GMe had a lower pain threshold, which was in line with the current study.

Trigger points of GMe lead to muscle weakness. Keeping this notion in mind, one must retrain the GMe muscle along with regional strengthening exercises to manage PFPS rather than just focussing on the joint.

Unfortunately, rather than treating the cause of this muscle weakness, earlier researchers focussed on treating the symptom of weakness, and that is why the results showed significant reductions only for pain and improvement in physical function, but showed no improvement in terms of strength. In some studies, strength did increase, but the intervention was for >6 weeks although an average of 6 weeks is a principal factor for strength training programmes, which was the total intervention length of the current study.

It is important to note that when a tissue that contains MTrPs is exercised prior to deactivation, the referred pain is frequently induced or amplified. Hence, treatment of MTrPs should precede the exercise therapy to prevent its reactivation as the function of the tissue will return to normal.

Roach et al. observed no significant increments in the strength after trigger point therapy because they used a different technique, and, as such, comparison with current data is difficult. The fact that no increments in strength were observed can be because no strengthening exercises were incorporated, or the trigger point treatment was not effective.

Conversely, another study combined dry needling with exercise therapy, and found more beneficial effects than exercises therapy alone. The comparison with that study could not be done fully due to a different treatment for MTrPs, but the fact that they treated the trigger point prior to the exercise therapy is evidence that eliminating the cause of muscle weakness prior to strengthening was beneficial, significantly decreasing pain, improving function and PPT, and increasing muscle strength.
PRT and MFRT have been recognised as valuable treatment options. Comparison of both has been done in 2 studies, with one study finding PRT more effective and the other favouring MFRT.

The effectiveness of PRT for treating MTrPs has been well-established. It also demonstrated superior effects when compared to other techniques, whereas some studies have stated otherwise. PRT also increases strength alone, which gives us an insight as to why the PRT group showed a more significant increase in strength. In support of the current research, the benefits of PRT are assumed to be derived from an automatic resetting of muscle spindles which would help to dictate the tone and length of the affected tissues as well as increase the length of sarcomeres in the contraction knot area. The manual contact component can also be responsible for improvements in PPT and reductions in local pain intensity.

On the other hand, MFRT has also been effective in treating MTrPs. The protocol of MFRT is variable and requires a longer time which is not possible to achieve in clinical outpatients settings, so 6 MFRT sessions lasting 5-10 minutes each were given to achieve a therapeutic effect. MFRT was found to be effective in treating MTrPs in a few studies, while others found it to be inferior. MFRT is used over the MTrPs that cause fascial restrictions. It influences the autonomic nervous system by creating a positive shift from sympathetic to parasympathetic response, contacting Transforming Growth Factor-beta (TGF-β), improving the immune response and increasing interleukin-3 (IL-3), ultimately regulating blood cell production.

Myofascial release, as a trigger-point treatment, has been used by many researchers, but no definite mechanism has been defined. Therefore, the current study tried to explain the mechanism, using available background history. Fascia plays a key role in muscle contractility and formation of MTrPs. It moves in response to muscle activity and provides proprioception that is essential for postural integrity. Under continuous stress, like prolonged postural or muscle overload, it binds down, creating fascial restriction, and causing postural imbalances. Neural and vascular restrictions also occur because all the important nutrients or circulatory exchange is done via the fascia. It is important to note that muscles distribute their contractile tension forces onto the fascial network. Deep fascia has mechanoreceptors and nociceptors that are sensitised by mechanical or chemical stimulation, like prolonged posture, muscle contraction, overuse or overload. Because the fascia functions along with the muscle fibre it covers, any problem in the muscle can affect the fascia equally. This is why myofascial trigger point was the term coined by Travells. Treatment MTrPs must involve manipulation of the fascia, because it cannot be isolated from the muscle. Based on these findings, the current study concluded that MFRT is a valuable manual therapy technique for treating MTrPs. Thus, when combined with a strengthening programme, it can yield better outcomes, as reported currently.

The findings corroborated the beneficial effects of strengthening exercises of combined hip and knee musculature, rather than knee exercises alone, to reduce pain and improve function. These exercises may optimise the motion and alignment of the pelvic and knee, thus ultimately decreasing patellofemoral joint stresses, improving the kinetics and kinematics of lower extremities, and enhancing tissue-healing which has been observed after exercise therapy. As far as the type of strengthening exercises are concerned, to date, there is no specific type to be described.

QOL is another crucial factor that impacts individuals with PFPS. To date, no study has used WHOQOL-BREF to measure QOL in PFPS. Evidence suggests that QOL can improve PFPS following exercise therapy, which was in line with the current findings.

The study’s findings are consistent with a recent consensus statement on PFPS management, which advocates a combination of knee and hip-focussed exercise therapy. Furthermore, the current study revealed that targetting MTrPs in proximal muscles, like GMe, relative to the affected knee could be a useful adjunct treatment for unilateral PFPS. However, further research is required in this regard.

The current study has limitations. The Urdu version of AKPS was not available, and it was translated with the help of language experts. Thus, cross-cultural validation was not possible. Further studies on PFPS should be conducted with larger sample sizes to generate findings that are more appropriately generalisable.

**Conclusion**

Both PRT and MFRT were found to be equally effective in alleviating MTrPs of GMe when used in conjunction with exercise therapy to reduce pain, and improve function, PPT, muscle and QOL. However, no technique was superior to the other.

**Acknowledgement:** We are grateful to our parents, friends, and supervisors for keeping us motivated throughout the trial.
Reason for early date of recruitment: Though the approval was taken in the pre-covid era, the work could not be started immediately and it was delayed for 10 months due to the Covid pandemic.

Supplier

a. Hoggan Scientific LLC, 3653 West 1987 South, Salt Lake City, UT 84104.

Disclaimer: None.

Conflict of Interest: None.

Source of Funding: None.

References

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**Author’s Contributions**

**PRK:** Concept, data collection, literature review, study design, discussion and drafting.

**RRS:** Concept, study design, data analysis, interpretation, proofreading and drafting.

Both authors are accountable for all aspects of the work.