

## Clinical Prediction Rules in Physical Therapy: Coming of Age?

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We thank Dr Fritz for her editorial<sup>8</sup> on clinical prediction rules (CPR) in general, as well as her specific comments related to our study, "Predicting Short-Term Response to Thrust and Nonthrust Manipulation and Exercise in Patients Post Inversion Ankle Sprain."<sup>15</sup> Her editorial and our response can only help to stimulate further important discussion regarding research design and potential clinical implications of published research. We will respond to the comments directly related to our study, specifically addressing our rationale for seeking to identify a clinical prediction rule (or guideline) for individuals who have sustained an inversion ankle sprain.

While it is generally accepted that "functional" treatment is superior to immobilization for patients with ankle sprain, the role that manual therapy could, or even should, play in the management of these patients is unclear.<sup>11</sup> As Dr Fritz pointed out, systematic reviews of interventions for patients post inversion ankle sprains advocate a management strategy of early mobilization (or "don't immobilize"), exercise, and manual therapy.<sup>2,10,14</sup> Although we agree that this is the general treatment approach typically advocated for nonsevere (grade I and II) sprains, we do not believe that manual physical therapy has strong or even moderate research support in treating patients with ankle sprain. Specifically, none of the studies in the systematic review by Jones and Amendola<sup>10</sup> included manual therapy interventions. While 2 additional reviews<sup>2,14</sup> support the premise that manual therapy may assist in improving dorsiflexion range of motion; unfortunately, it is unknown whether this translates to improved function or diminished pain. Randomized clinical trials performed to

date investigating the effects of thrust and/or nonthrust manipulation interventions for patients with ankle sprain have suffered from substantial methodological flaws, including no blinding of assessors, no assessment of function or disability, and no intention-to-treat analysis in the face of marked dropout rates.<sup>6,9,12</sup> As we noted in our manuscript, only 1 clinical trial has investigated the impact of manual therapy on function.<sup>12</sup> Even these results must be interpreted cautiously, as the assessors in this study were not blind to group assignment, subjects who suffered reinjury during the study were excluded from the data analysis, and no intention-to-treat analysis was performed to account for the 5 subjects who did not complete the study.<sup>12</sup> In the end, we are left with moderate support that manual therapy can be beneficial for improving a physical impairment (dorsiflexion range of motion), weak support for improving function, and no idea of who would benefit the most from manual therapy interventions, especially thrust techniques. In fact, the authors of a current orthopedic physical therapy textbook make no mention of the use of manual therapy for the treatment of ankle sprains.<sup>5</sup>

Many of us who treat patients with ankle sprain will attest to the fact that the inclusion of manual therapy interventions seems to be the "magic bullet" that helps certain patients make substantial gains. Yet the same approach for other patients seems to make no difference in their overall progress. Why is this? As clinicians who routinely treat patients with ankle sprain, we argue that this is not a homogeneous condition as suggested by Dr Fritz. Our collective clinical experience suggests that there may in fact be subgroups who would respond best to the inclusion of manual therapy techniques (including thrust techniques), while the inclusion of these techniques may not be helpful or perhaps even result in a worsening in status for others. This collection of clinical observations and opinions led to the CPR derivation study conducted by our group. As with other

CPR derivation studies,<sup>3,4,7</sup> we included manual therapy techniques as well as a very basic mobility program and advice to stay active. Patient education on rest, ice, compression, elevation (RICE) was also included based on the fact that a RICE approach is believed to be a standard of care for patients with a status of post acute ankle sprain, and we anticipated enrolling some patients with recent sprains. Our expectation was that we would identify an initial CPR that would differentiate those who did well with this intervention approach compared to those who did not do well. These findings would have not only provided preliminary guidance to clinicians on when to use this treatment approach, but also would have been helpful in designing follow-on clinical trials. In a recent editorial in *JOSPT*, Dr Simoneau<sup>13</sup> stated that the "process reflects the necessary systematic and incremental creation of new knowledge." He further stated that "while acknowledging the limitations of clinical prediction rules, there is certainly reason to be optimistic about the potentially useful information that the ability to characterize baseline attributes of patients who may respond to specific interventions may provide clinicians."<sup>13</sup>

Beneciuk et al<sup>1</sup> recently published a systematic review of CPRs for physical therapy interventions, providing an initial guideline for judging the quality of CPR derivation studies for physical therapy interventions. Interestingly, our CPR study<sup>15</sup> meets the majority of the 18-item list of criteria proposed by Beneciuk et al.<sup>1</sup> Had our study been included in the systematic review, it would have met the operational definition for a high-quality CPR study with a score of over 60%. We agree with Beneciuk et al,<sup>1</sup> as well as with Dr Fritz, that we, as a profession, should continue to work on elevating the quality of CPR derivation studies, including immediate follow-up with validation studies, longer-term follow-up, use of blinded assessors, etc. We also agree with Beneciuk et al<sup>1</sup> and Dr Fritz that there is a lack of consensus as to what constitutes

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a methodologically sound CPR, especially in the derivation stage.

As sometimes is the case with clinical research, the results of our study, showing that 75% of patients achieved “success” (a self-rating of at least “quite a bit better”) after only 1 or 2 treatment sessions were somewhat unexpected, and yet exciting. As pointed out by Dr Fritz, further examination of the results showed that 73% of the patients who did not meet the CPR developed in the study had a successful outcome, compared to an 85% success rate for those who met the CPR. Indeed, we are left with a situation where one may ask what can be gained from the results? How will these results be used to guide my clinical practice? If the results had been different, such as those meeting the CPR experiencing a successful outcome 95% of the time, while those not meeting the CPR achieving success only 40% of the time, we would have more clearly defined implications for clinical practice. Additionally, a subgroup could have emerged that experienced a worsening of status with this “package,” and this would have helped us stratify the risk associated with these interventions. With these theoretical results, we would have been able to clearly define the subgroup who should ideally receive a program including thrust and nonthrust manipulation, advice to stay active, RICE, and a basic mobility program. This group would have been well differentiated from those who did not respond as well to this package of interventions and, therefore, for whom another approach might have been better. Alternative interventions that might have been a better fit for this subgroup could have included strengthening and conditioning exercise, balance and proprioceptive exercises, speed and agility drills, etc.

Despite the unexpected results from our trial, we believe our study generated positive new information related to the management of individuals with acute/subacute ankle sprains. First, despite the common thought amongst physical therapists that manual therapy may actually

hurt these patients (especially thrust manipulation), our results show that a program that includes thrust and nonthrust manipulation can be used in patients with a status of post ankle sprain without increasing pain or harming the patient. In fact, no patients reported a worsening in status, they just didn't meet our definition of “success” (a self-rating of at least “quite a bit better”). While a different rehabilitation program potentially would have been better for these subjects, they did not worsen with a program including thrust and nonthrust mobilization/manipulation. Next, we provided evidence that the majority of patients who are post ankle sprain do well in the short-term with a program that includes thrust and nonthrust manipulation, advice to stay active, RICE, and a basic mobility program. Finally, the CPR, while not clearly delineating groups of responders and nonresponders as initially expected, may still be helpful for the purpose of prognosis for those with 3 of 4 variables (95% posttest probability) and those at the other end of the range with 0 to 1 predictor variables (55% posttest probability). In summary, despite the surprising results of our study, we are excited about our findings and the potential implications for clinicians and researchers alike.

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## Frontal Plane Measurements During a Single-Leg Squat Test in Individuals With Patellofemoral Pain Syndrome

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We read with great interest the paper "Utility of the Frontal Plane Projection Angle in Females With Patellofemoral Pain," published in the October 2008 issue of the *JOSPT*.<sup>9</sup> It is believed that individuals with patellofemoral pain syndrome (PFPS) demonstrate abnormal lower extremity mechanics.<sup>1,6</sup> These altered frontal- and transverse-plane hip, knee, and foot kinematics during weight-bearing activities have been previously described as leading to "medial collapse" of the knee.<sup>3-6</sup> Willson and Davis<sup>9</sup> nicely addressed the importance of developing a reliable and practical test for patients with PFPS for use in a clinical testing. The authors also discussed previous studies that investigated measurements of lower extremity alignment during a single-leg squat test in asymptomatic individuals.<sup>10</sup> More specifically, the authors proposed the use of the frontal-plane projection angle in patients with PFPS to evaluate the medial collapse of the knee. Levinger et al<sup>4,5</sup> recently published their work investigating such a test. The femoral frontal angle was aimed at investigating the medial displacement of the knee in individuals with PFPS. We showed that the femoral frontal angle was a reliable test and that individuals with PFPS demonstrated an increased medial de-

viation of the knee, as represented by a larger angle. We believe that the femoral frontal angle test is useful and reliable and can be used as an objective measure of lower extremity alignment in individuals with PFPS.

Factors distal to the patellofemoral joint can also contribute to the altered alignment of the knee in the frontal plane.<sup>2,5,7,8</sup> Due to the coupling motion between the rearfoot and tibia, abnormal motion of the foot can affect tibial transverse- and frontal-plane motion.<sup>6</sup> Although Willson and Davis<sup>9</sup> provided insight into the mechanism responsible for the medial collapse of the knee by investigating the 3-dimensional lower extremity joint rotation (locally and proximally), they neglected to acknowledge the possible contribution of the foot to this phenomenon. Recently, we have reported increased rearfoot eversion during a single-limb squat test in individuals with PFPS.<sup>5</sup> We believe, therefore, that altered foot function in individuals with PFPS may contribute to the medial collapse of the knee and should be acknowledged. Future studies on this topic should be directed towards simultaneous evaluation of proximal and distal lower extremity kinematics to fully understand the mechanism involved in the medial collapse of the knee in individuals with PFPS.

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## RESPONSE

We appreciate the opportunity to reply to the commentary provided by Levinger and Gilleard regarding our recent analysis of a clinical measure of lower extremity alignment in females with patellofemoral pain. It is affirming to read that, despite differences in methodology between the study by Levinger and Gilleard<sup>4</sup> and ours, both studies independently reached similar conclusions regarding medial collapse of the knee among patients with patellofemoral pain syndrome (PFPS). We echo the sentiment of these authors that 2-dimensional techniques can be an objective and reliable indicator of lower extremity kinematics that may contribute to either the exacerbation or etiology of PFPS. We believe such methods offer clinicians a superior option to subjective assessment of lower

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extremity alignment during weight-bearing activities for their patients.

Levinger and Gilleard highlight the potential for distal joint motion to contribute to medial collapse of the knee among patients with PFPS. We agree with these authors that it is conceivable that factors distal to the knee contributed to increased medial collapse of the knee during the single-limb squat test in our study. The models referenced in the commentary of increased foot pronation causing increased tibial internal rotation or calcaneal eversion causing tibial abduction are widely known.<sup>8,11</sup> Unfortunately, despite the popularity of these models, evidence of foot pronation or calcaneal eversion causing predictable effects in the transverse or frontal plane at more proximal segments or joints is scant and inconsistent.<sup>1,2,3,6,7,9,10,13</sup> Methodological differences among studies investigating this potential relationship with respect to footwear, foot and ankle models or joint coordinate systems, ankle joint degrees of freedom, and limitations in surface-based 3-dimensional motion analysis likely contribute to the conflicting results. Additionally, between-subject variability in the pitch of the subtalar joint axis will also obscure this possible relationship.<sup>12</sup> This is not to say a relationship between foot and knee motion does not exist. Rather, it is likely that authors of many previous studies on this topic have not been consistently successful in quantifying it.

The contribution of proximal or distal joint mechanics on increased medial collapse of the knee among patients with PFPS in our study is unknown. Identifying the cause of this altered movement pattern was not the purpose of our study. However, in the discussion of our results, we hypothesized that hip weakness or diminished or delayed neuromuscular activation of hip musculature among individuals with PFPS may contribute to increased medial collapse of the knee. Clearly, the nonexperimental design of our recent study prohibits development of a cause-and-effect relationship for

medial collapse of the knee during single-limb squats among patients with PFPS. Indeed, Levinger and Gilleard<sup>8</sup> acknowledge this same limitation in their own previous work by noting that their results do not clarify if increased rearfoot eversion among patients with PFPS is a cause or effect of increased medial collapse of the knee. Therefore, until consistent experimental evidence to the contrary exists, we encourage clinicians to consider the potential for both proximal and distal joint mechanics to contribute to altered knee joint kinematics during the assessment of their patients with PFPS. Further experimental research is necessary to delineate the extent of the influence of both proximal and distal joint mechanics to these altered lower extremity kinematics.

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### Management of Patients With Patellofemoral Pain Syndrome Using a Multimodal Approach: A Case Series

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I would first like to congratulate Lowry and colleagues<sup>2</sup> on the publication of their case series in the November 2008 issue of the *JOSPT*. The study provides an opportunity to discuss clinical concepts and treatment techniques aiming at improving patient outcomes in those with patellofemoral pain. The article does have some potential concerns, and I appreciate the opportunity to comment on this study with the hope of stimulating discussion.

A clinical decision-making approach

to patellofemoral pain suggests that one begin with a working hypothesis related to factors contributing to the pathological state. The next step would then be to alter the potential contributing factors and reassess. For instance, if a patient were negotiating stairs with excessive femoral internal rotation and adduction (a theoretical contributing factor to the development of patellofemoral pain),<sup>4</sup> the clinician would aid in correcting this pathomechanical position. If symptoms decreased as a result of that intervention, this would lend support to the idea that femoral internal rotation and adduction were contributing to patellofemoral pain in this patient.

The authors failed to give a viable hypothesis as to why certain impairments are potential factors in the etiology of patellofemoral pain. For instance, they noted joint restrictions throughout the hip, patella, and tibiofibular joints, but they leave readers pondering as to why these restrictions would be problematic, specifically at the tibiofibular joint. Additionally, I was curious as to why the authors chose not to report on talocrural joint mobility, despite noting a lack of ankle dorsiflexion in some patients. Lack of ankle dorsiflexion has been shown to increase frontal-plane excursion at the knee.<sup>5,6</sup> Increased frontal-plane excursion at the knee has been linked to patellofemoral pain.<sup>3,4</sup>

The authors were also unsuccessful in consistently reporting re-evaluation after treatment. While they reassessed a step-down after taping the patella medially, no such reassessment of pain, joint restriction, or biomechanical change was documented in the article immediately following their manual techniques. As readers, we do not know if joint mobility changed after treatment and if this change was associated with an improvement in pain status and/or movement strategy.

I was particularly concerned as to why the authors chose to manipulate the lumbopelvic spine in all 5 patients. The article stated that “thrust and nonthrust

manipulation directed at the lumbopelvic spine, hip, patellofemoral, and proximal tibiofibular joints was performed if a restriction with joint mobility was noted...” While limitation in hip, patella, and tibiofibular joint play was reported, a restriction in lumbopelvic mobility was not; yet the authors chose to manipulate this area regardless. Moreover, the article suggested that patient 1 reported “pain with walking, squatting, running, and sitting less than 20 minutes.” Upon physical exam she demonstrated “no excessive pronation and less than 3-mm navicular drop in single-limb standing... and hip rotation side-to-side difference of 8°.” She presented with none of the criteria that satisfy the clinical prediction rule stated by Iverson et al<sup>1</sup> in those with patellofemoral pain who would benefit from a lumbopelvic manipulation. It is unclear why the authors chose to manipulate her lumbopelvic spine.

In a more detailed analysis of the data, if the authors were to present all 7 cases, 5 out of the 7 patients (2 patients were excluded for reasons explained later) did not experience a change in their worst reported pain 4 visits after manipulation. Also, only 2 out of 4 patients who presented with hip internal rotation deficits greater than 14° improved post manipulation at 4 visits. We as readers cannot be certain as to why these patients improved, as it could be attributed to excellent patient education, avoiding aggravating activity, manual intervention, change in medication status, etc. While Iverson et al<sup>1</sup> demonstrated that 80% of patients who had hip internal rotation deficits greater than 14° improved on the Numeric Pain Rating Scale immediately postmanipulation, they did not follow up after their initial reassessment. It seems that Lowry et al’s<sup>2</sup> report questions long-term change in those with patellofemoral pain treated with lumbopelvic manipulation, reaffirming that the prediction rule by Iverson et al<sup>1</sup> needs further validation.

Finally, the exclusion criteria stated in the section titled “Case Description” eliminate logical confounding variables,

such as anterior cruciate ligament rupture. However, in the “Outcomes” section the authors reported that they excluded 2 other patients “due to the mechanism of injury being a traumatic event, and the other due to time constraints.” I am having difficulty understanding why data were excluded in a patient with a trauma-induced mechanism of injury, particularly because this was not part of the original exclusion criteria.

While I applaud the authors’ efforts in bringing this information to the literature, I recommend that future studies demonstrate a clearly delineated systematic approach in the decision-making process to aid clinicians in evaluating and treating patellofemoral pain. I also encourage clinicians to be mindful when considering manipulation of the lumbopelvic spine as a viable treatment option in patients with patellofemoral pain based on the currently limited available literature.

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## LETTERS TO THE EDITOR-IN-CHIEF (CONTINUED)

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### RESPONSE

First, we would like to thank Dr Hensley for his comments and the editors at *JOSPT* for the opportunity to respond regarding our manuscript "Management of Patients With Patellofemoral Pain Syndrome Using a Multimodal Approach: A Case Series."<sup>3</sup> Dr Hensley raises several good points, and we hope that our response continues to facilitate reflection and discussion on the mechanisms behind manual therapy.

Dr Hensley presents an argument that it is essential to identify a biomechanical fault underlying a patient's patellofemoral pain. While we agree that there may be biomechanical impairments present in patients with patellofemoral pain syndrome (PFPS),<sup>7</sup> we caution overemphasizing the need to identify a specific radiographic pathology or a biomechanical fault prior to commencing treatment. In the clinical setting, the practitioner often may not identify the exact etiology of a patient's pain; nor does knee pathology necessarily mean that the patient will have pain. For example, radiographic evidence of knee osteoarthritis has been shown to exist in 17% of asymptomatic subjects.<sup>6</sup> While we agree the hypothesized biomechanical measures of subtalar pronation, Q-angle, internal tibial rotation, internal femoral rotation, knee valgus,<sup>7</sup> and knee frontal-plane excursion<sup>8</sup> may affect patellar biomechanics, these measures need further research to determine if altering them may lead to pain relief in patients with PFPS. The purpose of this case series was simply to describe the outcomes of 5 patients treated with manual therapy, taping, exercise, and orthotic prescription rather than hy-

pothesize about potential causes of patellofemoral pain or mechanisms of manual therapy.<sup>3</sup>

We believe that current evidence supports a manual therapy pain relief mechanism not necessarily based solely upon biomechanical explanations but rather neurophysiological mechanisms stimulated by a novel mechanical input.<sup>1</sup> Basic science research in an animal model demonstrates that knee joint manipulation activates a cascade of neurotransmitters, which activate pathways utilizing serotonin and noradrenaline.<sup>9</sup> Direct evidence for both spinal cord modulation and a supraspinal response to knee joint manipulation have been seen using functional magnetic resonance imaging in rats.<sup>4,5</sup> These basic science studies support clinical findings of increased pain pressure thresholds and hypoalgesia following manual therapy.<sup>10</sup> Due to the evidence supporting manipulation for pain relief, the authors propose that the tibiofibular manipulation used in this case series may have exerted a similar neurophysiological effect to relieve pain with knee flexion. Concordantly, the effect of each manual therapy technique was assessed in this study using a pretest-posttest assessment; however, due to word limitations and feedback throughout the manuscript peer-review process, the effects of each specific manipulation was not included in the manuscript. In general, there was decreased pain and improved motion after most of the manual therapy techniques, which could have been a result of a neurophysiological response to mechanical stimuli.<sup>1</sup>

Specifically, Dr Hensley questioned the use of lumbopelvic manipulation in the treatment of these 5 patients with patellofemoral pain. The 2 patients that Dr. Hensley mentioned that were excluded from our case series based on eligibility criteria did not sign informed consent; therefore, the actual cases cannot be discussed. In general, the patient with the traumatic event had factors that led the clinician to determine the

mechanism of injury was not consistent with the clinical picture of an insidious, overuse mechanism of classic PFPS, and this subject was excluded. The second patient excluded from the case series was unable to attend regular physical therapy visits. Of the 5 patients recruited for this case series, patient 1 met 1 of the criteria for the clinical prediction rule for lumbopelvic manipulation.<sup>2</sup> She reported squatting as the most painful activity, which improves the posttest probability of responding to lumbopelvic manipulation to 47%.<sup>2</sup> Considering that the patient had no contraindications or precautions for lumbopelvic manipulation, the risk-benefit ratio clearly favored the benefit of manipulation for pain relief with this patient. Unfortunately, patient number 1 was not a responder to manipulation. Despite this single patient response and the fact that the clinical prediction rule<sup>2</sup> has yet to be validated, we continue to believe that manipulation may provide immediate pain relief and may be applied in an effective, safe, and expedient manner in the appropriately screened patient.

Once again, we thank Dr Hensley for raising pertinent queries regarding our case series. Future studies should explore validation of the clinical prediction rule,<sup>2</sup> investigate long-term effects of manipulation, and examine the role of the foot and ankle within the regional interdependence model, as Dr Hensley suggested. While we agree that future studies should explore the clinical decision-making process in treating patellofemoral pain, we also believe that these studies should be based upon the most current pain theories to encompass the neurophysiological effects of manual therapy at the peripheral, spinal, supraspinal, and psychological levels for pain relief.

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