JOSPT PERSPECTIVES FOR PATIENTS

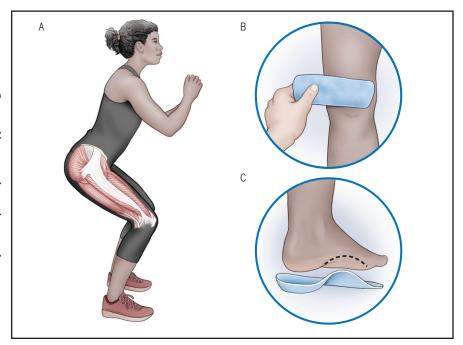
Patellofemoral Pain

Treating Painful Kneecaps

J Orthop Sports Phys Ther 2019;49(9):633. doi:10.2519/jospt.2019.0504

ain under the kneecap is one of the most common reasons people seek health care. The pain, which is also known as anterior knee pain or patellofemoral pain, is often described as a nagging ache or occasional sharp twinge. You may feel this type of pain most after sitting for a long time, going up and down stairs, jumping, or running—especially on hills. Kneecap pain can affect your participation in physical activity, sports, or work, which can be frustrating.

The good news is that most people with this type of knee pain find it gets better. Guidelines published in the September 2019 issue of the *JOSPT* make recommendations for diagnosing, measuring, and treating kneecap pain. Ultimately, the best care is a combination of the best science, the expertise of your health care provider, and your preferences and values. These guidelines help you and your health care provider make the best decision for you.



EASING KNEECAP PAIN. Knee pain that is in the front of your knee or under your kneecap is often called patellofemoral pain. Strengthening exercises that focus on your hip and thigh muscles, such as squats, are more likely to get you back to feeling like yourself (A). Your physical therapist may also apply tape to your kneecap early in your treatment to help reduce pain and improve function (B). Shoe inserts that you can buy in a store might help to manage kneecap pain in the early weeks of your treatment (C).

This JOSPT Perspectives for Patients is based on clinical practice guidelines by Willy et al titled "Patellofemoral Pain" (J Orthop Sports Phys Ther. 2019;49(9):CPG1-CPG95. https://doi.org/10.2519/jospt.2019.0302).

This Perspectives article was written by a team of *JOSPT*'s editorial board and staff. Deydre S. Teyhen, PT, PhD, OCS, Editor, and Jeanne Robertson, Illustrator.

For this and more topics, visit JOSPT Perspectives for Patients online at www.jospt.org.

NEW INSIGHTS

To develop these guidelines, expert clinicians and researchers reviewed about 4500 scientific articles about kneecap pain published between 1960 and May 2018. They chose the best research for the guidelines (271 articles) about the risk factors, diagnosis, examination, outcome measures, and nonsurgical treatment options for kneecap pain.

The best treatment is a combined program of hipand knee-strengthening exercises. The combined strengthening exercises were better for reducing pain and helping people return to their normal activities than strengthening the knee muscles alone. Off-theshelf shoe inserts might help some people manage kneecap pain in the first 6 weeks, when combined with exercises such as squats. Taping the painful kneecap, in combination with exercises, may help some people manage kneecap pain and get back to their normal activities in the first 4 weeks of therapy.

PRACTICAL ADVICE

Most people with kneecap pain get better with physical therapy. That's great news! A holistic approach that combines education, strength exercises, taping, shoe inserts, and kneecap mobilizations is likely to bring the best results. To help guide your treatment and tailor a program to your needs, your physical therapist will ask you about your kneecap pain and perform a thorough evaluation. Depending on the findings, you may be prescribed a combination of hip- and kneestrengthening exercises. Taping your kneecap or adding inserts to your shoes may also help to manage kneecap pain early in treatment (the first 4-6 weeks).

Your physical therapist can help tailor a treatment program to reduce symptoms, and help you return to your desired activities, sports, or work.



JOSPT PERSPECTIVES FOR PATIENTS is a public service of the Journal of Orthopaedic & Sports Physical Therapy. The information and recommendations contained here are a summary of the referenced research article and are not a substitute for seeking proper health care to diagnose and treat this condition. For more information on the management of this condition, contact your physical therapist or other health care provider specializing in musculoskeletal disorders. JOSPT Perspectives for Patients may be photocopied noncommercially by physical therapists and other health care providers to share with patients. The official journal of the Academy of Orthopaedic Physical Therapy and the American Academy of Sports Physical Therapy of the American Physical Therapy Association (APTA) and a recognized journal of 36 international partners, JOSPT strives to offer high-quality research, immediately applicable clinical material, and useful supplemental information on musculoskeletal and sports-related health, injury, and rehabilitation. Copyright ©2019 Journal of Orthopaedic & Sports Physical Therapy.

JOSPT PERSPECTIVES FOR PRACTICE

Patellofemoral Pain

Using the Evidence to Guide Physical Therapist Practice

J Orthop Sports Phys Ther 2019;49(9):631-632. doi:10.2519/jospt.2019.0503

neecap pain, also known as anterior knee pain or patellofemoral pain, is the most common injury seen in sports medicine clinics. People with patellofemoral pain describe a gradual onset that typically occurs after a sudden increase in strenuous activities—often involving running, jumping, or repetitive squatting. Once a person begins experiencing symptoms,

even simple activities, such as prolonged sitting or descending stairs, can be difficult. Imaging, such as knee magnetic resonance imaging, is not helpful in identifying patellofemoral pain. Clinicians diagnose patellofemoral pain by assessing movements that are painful, such as squatting, and after ruling out other possible conditions, including iliotibial band pain and patellar tendinopathy.

WHAT WE KNEW

The goal of the clinical practice guidelines on patellofemoral pain, published in the September 2019 issue of the JOSPT, was to make recommendations based on best scientific evidence that help clinicians and patients make decisions about managing this pain. Clinicians can use these guidelines to combine the latest scientific evidence with their clinical expertise and the preferences of the patient to develop a tailored management plan.

WHAT WE DID

Researchers and expert clinicians searched for all relevant clinical research published from 1960 through May 2018. After screening approximately 4500 articles, the review team selected the best research (271 articles) on patellofemoral pain. The review team formulated recommendations for best practice in diagnosis, classification, measuring outcomes, and nonsurgical treatment for people with patellofemoral pain.

WHAT WE FOUND

Physically active women are more likely to develop patellofemoral pain compared with physically active men. Specializing in a single sport may double the risk of experiencing patellofemoral pain. Thigh muscle weakness may also increase the risk of patellofemoral pain. Height, body weight, and foot posture do not predict who will develop this pain. Because patellofemoral pain typically does not resolve without appropriate treatment, people with this pain should seek appropriate care.

BOTTOM LINE FOR PRACTICE

Exercise therapy that is appropriately progressed and focused on hip and knee strengthening is the best approach to managing patellofemoral pain. Patellar taping or inexpensive shoe inserts may be helpful, but only when used in combination with high-quality exercise therapy.

Passive treatments, such as ultrasound, electrical stimulation, spinal manipulation, and dry needling, are not helpful for managing patellofemoral pain and should not be used. Physical therapists can help patients when they are returning to their desired activities by guiding patients to slowly increase the frequency, intensity, and duration of activities that load the knee.

This JOSPT Perspectives for Practice was written by a team of JOSPT's Special Features Editor: Perspectives for Practice Alexander Scott, BSc(PT), PhD, and staff, led by Editor-in-Chief Clare L. Ardern, PT, PhD. The flow chart on the following page was produced by Kate Minick, PT, DPT, OCS, of Intermountain Healthcare, Rehabilitation Services, Salt Lake City, UT.

For this and more topics, visit JOSPT Perspectives for Practice online at www.jospt.org.

REFERENCE

1. Willy RW, Hoglund LT, Barton CJ, et al. Patellofemoral pain. J Orthop Sports Phys Ther. 2019;49:CPG1-CPG95. https://doi.org/10.2519/jospt.2019.0302



JOSPT PERSPECTIVES FOR PRACTICE is a service of the Journal of Orthopaedic & Sports Physical Therapy®. The information and recommendations summarize the impact for practice of the referenced research article. For a full discussion of the findings, please see the article itself. The official journal of the Academy of Orthopaedic Physical Therapy and the American Academy of Sports Physical Therapy of the American Physical Therapy Association (APTA) and a recognized journal with 36 international partners, JOSPT strives to offer high-quality research, immediately applicable clinical material, and useful supplemental information on musculoskeletal and sports-related health, injury, and rehabilitation. Copyright ©2019 Journal of Orthopaedic & Sports Physical Therapy®

JOSPT PERSPECTIVES FOR PRACTICE

Patellofemoral Pain Care Process Model Diagnosis/Classification of Patellofemoral Pain: Evaluation of Clinical Findings Diagnostic criteria - B Presence of retropatellar or peripatellar pain, AND 2. Reproduction of retropatellar or peripatellar pain with squatting, stair climbing, prolonged sitting, or other functional activities loading the patellofemoral joint (PFJ) in a flexed 3. Exclusion of all other conditions that may cause anterior knee pain Diagnostic tests Reproduction of pain with squatting and other functional activities that load the PFJ in a flexed position (eg, stair climbing or descent) - A · Patellar tilt test with presence of hypomobility - C Overuse/Overload Without Other **Movement Coordination Deficits Mobility Impairments** Muscle Performance Deficits Impairment Lower extremity (LE) muscle Foot hypermobility and/or flexibility History of an increase in magnitude Excessive/poorly controlled knee valgus and/or frequency of PFJ loading at a performance deficits in the hip and during dynamic task not due to deficits of at least 1 of hamstrings, rate that surpasses PFJ recovery - F quadriceps - F weakness - F quadriceps, gastrocnemius, soleus, lateral retinaculum, or iliotibial band - F **Assessment** Patient-reported outcome measures - A Physical impairment measures - C Physical performance measures - B AKPS, KOOS-PF, or VAS for activity (EPQ) Clinical/field tests that reproduce pain and assess Patellar provocation questionnaires to measure pain and function Patellar mobility LE movement coordination (eg, squatting, VAS for worst pain, VAS for usual pain, or NPRS to Foot position step-downs, and single-leg stance) Hip and thigh muscle strength measure pain Muscle length **Intervention Strategies** Specific modes of exercise therapy - A Not recommended Combined hip- and knee-targeted exercises to reduce pain and improve Dry needling - A patient-reported outcomes and functional performance in the short, medium, and Manual therapy, including patellar or spinal mobilization, in isolation - A long term · Patellar taping with the aim of enhancing muscle function - B Hip exercise should target posterolateral hip musculature. Preference in early Patellofemoral knee orthoses (bracing) - B Biofeedback for quadriceps exercise - B Knee-targeted exercise includes either weight bearing or non-weight bearing Biofeedback for LE alignment during hip- and knee-targeted exercises - B Foot orthoses: prefabricated foot orthoses for greater-than-normal foot pronation to Biophysical agents, including ultrasound, cryotherapy, phonophoresis, reduce pain in the short term (6 weeks), in combination with exercise therapy - A iontophoresis, electrical stimulation, and therapeutic laser - B Combined interventions: clinicians may combine exercise therapy with other interventions (eg, foot orthoses, patellar taping, patellar mobilizations, and LE stretching) - A Patellar taping: with exercise therapy for pain reduction and enhanced exercise therapy outcomes in the short term (4 weeks) - B Running gait retraining: cuing for forefoot strike, increase in running cadence, or reduction in peak hip adduction - C Acupuncture: may use to reduce pain - C Patient education: may include load management, body-weight management, adherence to active treatments, biomechanics contributing to overload, evidence for treatment options, and kinesiophobia. May improve compliance and adherence - F Blood flow restriction training plus high-repetition knee-targeted exercise therapy: may use while monitoring for adverse events for those with painful resisted knee extension - F

Based on the guidelines, the grades in this flow chart may be translated as follows: A, strong evidence; B, moderate evidence; C, weak evidence; D, conflicting evidence; F, expert opinion. Figure produced for *JOSPT* by Kate Minick, PT, DPT, OCS, of Intermountain Healthcare, Salt Lake City, UT.

LETTER TO THE EDITOR-IN-CHIEF

Letters to the Editor are reviewed and selected for publication based on the relevance, importance, appropriateness, and timeliness of the topic. Please see submission guidelines at www.jospt.org.for further information. J Orthop Sports Phys Ther 2019;49(9):679-681. doi:10.2519/ jospt.2019.0201

HIGHLIGHTING DISTINCTIONS BETWEEN DISCRETE PERTURBATIONS AND CONTINUOUS PERTURBATIONS IN THE STUDY OF DYNAMIC TRUNK CONTROL

We thank the authors9 for this compelling work exploring the relevance of stability and instability to back pain. The article9 builds bridges between diverse interpretations and applications of these concepts, clarifies terminology and intent, and makes useful and creative applications of these concepts to pain processing and social factors. Specifically, we appreciate terms that were introduced or refined, including "mechanical" versus "control" stability, "lumbar intervertebral" versus "trunk" stability, and "trunkon-pelvis" versus "trunk-in-space" tasks. Investigating and discussing these concepts in a specific and accurate way are crucial to the continued advancement of research on the topic of back pain.

We believe the authors9 missed an opportunity in their discussion of dynamic control to highlight an important distinction between discrete mechanical perturbations and continuous mechanical perturbations. The authors9 describe an "evolution" from static to dynamic control concepts, but cite primarily experimental studies that utilized discrete perturbations to posture, such as seated trunk releases,1 sudden load applications or releases,4,6,7 and voluntary discrete limb movements.3 These discrete applications of force do not represent ecological challenges of coping with low-magnitude but continuously dynamic forces acting on an upright body. In addition, they are all trunk-on-pelvis control tasks done in standing or semi-seated with a fixed pelvis, while the authors9 call for more ecological trunk-in-space control tasks to be studied.

Continuous perturbations to the trunk represent a distinct "evolution" in control concepts applied to the trunk and back pain. In the section discussing dynamic stability, the authors9 cite a handful of studies that have utilized continuous perturbations, including pseudo-random perturbations to the trunk in standing,5 unstable seated balance,8 and supportsurface perturbations, inducing frontal plane pelvis tilts.2 The latter 2 of these may also qualify as trunk-in-space control tasks, where perturbations are delivered "bottom up," that is, through the pelvis.

Our goal in writing this letter is to bring attention to the important ecological and experimental differences between inducing discrete perturbations in a trunk-on-pelvis task and continuous perturbations from the "bottom up" in a trunk-in-space task. One such continuous task we developed is the balancedexterity task,10 which involves standing on one leg while trying to compress an unstable spring with the contralateral leg. In brief, the task acts as a continuous perturbation to single-limb stance, inducing multiplanar but primarily frontal plane perturbations to the pelvis. When 19 participants in remission from recurrent nonspecific low back pain completed the balance-dexterity task, their trunk coupling was associated with the ratio of lumbar multifidus activity to lumbar erector spinae activity, where those with more dissociated thorax and pelvis motion exhibited lower relative deep muscle (multifidus) activity.11 The finding that the deep-to-superficial paraspinal activation ratio was associated with trunk coupling in the balance-dexterity task agrees with and supports the suggestion by Reeves et al⁹ that deep-to-superficial trunk muscle coordination is important for dynamic stability.

We are not saying that the balancedexterity task is the perfect or only task to be used in the study of trunk control. In fact, we believe it is insufficient to investigate control in the transverse plane. It provides an example, along with the continuous support-surface perturbation tasks cited previously,2 of a continuous dynamic perturbation that requires participants to ecologically maintain trunk-in-space posture. We believe that investigating continuous, low-amplitude perturbations to posture will continue to elucidate ecological control strategies and relevant dysfunction in those suffering from back pain.

K. Michael Rowley, PhD Kornelia Kulig, PT, PhD, FAPTA Division of Biokinesiology and Physical Therapy University of Southern California Los Angeles, CA

The authors certify that they have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the letter.

REFERENCES

- 1. Cholewicki J, Silfies SP, Shah RA, et al. Delayed trunk muscle reflex responses increase the risk of low back injuries. Spine (Phila Pa 1976). 2005;30:2614-2620. https://doi.org/10.1097/01. brs.0000188273.27463.bc
- 2. Goodworth AD, Peterka RJ. Contribution of sensorimotor integration to spinal stabilization in humans. J Neurophysiol. 2009;102:496-512. https://doi.org/10.1152/jn.00118.2009
- 3. Hodges PW, Richardson CA. Inefficient muscular stabilization of the lumbar spine associated with low back pain. A motor control evaluation of transversus abdominis. Spine (Phila Pa 1976). 1996;21:2640-2650. https://doi. org/10.1097/00007632-199611150-00014
- 4. Magnusson ML, Aleksiev A, Wilder DG, et al. European Spine Society—the AcroMed Prize for Spinal Research 1995: unexpected load and asymmetric posture as etiologic factors in low back pain. Eur Spine J. 1996;5:23-35. https://doi. org/10.1007/bf00307824
- 5. Moorhouse KM, Granata KP. Role of reflex dynamics in spinal stability: intrinsic muscle stiffness alone is insufficient for stability. J Biomech.

LETTER TO THE EDITOR-IN-CHIEF

- 2007;40:1058-1065. https://doi.org/10.1016/j. jbiomech.2006.04.018
- 6. Radebold A, Cholewicki J, Panjabi MM, Patel TC. Muscle response pattern to sudden trunk loading in healthy individuals and in patients with chronic low back pain. Spine (Phila Pa 1976). 2000;25:947-954. https://doi.org/10.1097/00007632-200004150-00009
- Reeves NP, Cholewicki J, Milner TE. Muscle reflex classification of low-back pain. J Electromyogr Kinesiol. 2005;15:53-60. https://doi.org/10.1016/j. ielekin.2004.07.001
- Reeves NP, Cholewicki J, Narendra KS. Effects of reflex delays on postural control during unstable seated balance. *J Biomech*. 2009;42:164-170. https://doi.org/10.1016/j.jbiomech.2008.10.016
- Reeves NP, Cholewicki J, van Dieën JH, Kawchuk G, Hodges PW. Are stability and instability relevant concepts for back pain? J Orthop Sports Phys Ther. 2019;49:415-424. https://doi. org/10.2519/jospt.2019.8144
- Rowley KM, Gordon J, Kulig K. Characterizing the balance-dexterity task as a concurrent bipedal task to investigate trunk control during dynamic balance. *J Biomech.* 2018;77:211-217. https://doi. org/10.1016/j.jbiomech.2018.07.014
- 11. Rowley KM, Smith JA, Kulig K. Reduced trunk coupling in persons with recurrent low back pain is associated with greater deep-to-superficial trunk muscle activation ratios during the balance-dexterity task. J Orthop Sports Phys Ther. In press. https://doi.org/10.2519/jospt.2019.8756

RESPONSE

We thank Drs Rowley and Kulig for their interest in our recent publication³ and supportive comments. We regretfully missed an opportunity to include their contributions to the study of spine control and appreciate the occasion to comment on their letter to the editor to elaborate on an important issue.

As indicated in the manuscript,³ one of the goals was to highlight how systems-based approaches can be used to integrate knowledge. It is our opinion that the spine scientific community excels in creating knowledge but struggles, as do other disciplines, with its integration. To this end, a coherent framework is needed to synthesize current knowledge and future scientific discoveries to allow for a more complete and comprehensive view of back pain.

One of the key advantages of systemsbased approaches is the use of linear system theory to define system behavior. In theory, if a system is linear and time invariant, then the system can be defined using system identification techniques with knowledge of input (eg, perturbations) and output (eg, kinematic response). Once the system is defined, the response to any input can be simulated to predict the system's response. In this idealized world, the choice of continuous or noncontinuous input (ie, discrete) is irrelevant, as both would derive the same system through the system identification process. Unfortunately, human behavior typically is not linear and is often time varying, which makes the task of deriving the system more challenging. However, linear system theory can still be applied when these limitations are considered.

Although most physical systems are nonlinear and time varying, all systems have a range over which they exhibit linear time-invariant behavior. Over this range, linear time-invariant models can be generated to accurately represent system behavior. To capture the behavior of the system over its full operational range, multiple models are used. This is how complex systems such as aircraft are modeled and ultimately controlled.

Returning to the spine system, there is evidence that spine control is nonlinear4 and most likely time varying (eg, spine control changes with fatigue²). There are several interesting questions to be addressed: do people with back pain differ from healthy individuals in spine control over the entire operational range (ie, all models are different) or a small subset of the operational range (ie, single model around 1 operational point is different), or between operational points (ie, models around all operational points are the same, but switching between points is different)? Addressing these questions will rely on the proper choice of input signal to assess spine control. For instance, studying people with pain versus healthy people in regard to differences in spine control around a single point might benefit from small-amplitude, continuous perturbations, such as those proposed by Drs

Rowley and Kulig.^{5,6} In contrast, studying the switching phenomenon might benefit from large-amplitude, noncontinuous perturbations.¹ The proper framework informs methodological decisions and avoids confusion when discussing spine control in different contexts.

Finally, it is our hope that spine researchers will see the value of integrating knowledge, using the proposed system-based approach outlined in our paper,³ to better understand spine function and potential impairments due to back pain. Moving toward team science with a unified framework will improve our understanding of back pain and, more importantly, of outcomes for those afflicted, the ultimate goal for all stakeholders.

N. Peter Reeves, PhD Sumaq Life LLC East Lansing, MI

Jacek Cholewicki, PhD Center for Orthopedic Research Michigan State University Lansing, MI

Jaap H. van Dieën, PhD
Department of Human Movement Sciences, Vrije Universiteit Amsterdam
and Amsterdam Movement Sciences
Amsterdam, the Netherlands

Greg Kawchuk, DC, PhD
Department of Physical Therapy
Faculty of Rehabilitation Medicine
University of Alberta
Edmonton, Canada

Paul W. Hodges, PT, PhD, DSc Clinical Centre for Research Excellence in Spinal Pain, Injury and Health, School of Health and Rehabilitation Sciences The University of Queensland Brisbane, Australia

Dr Reeves is the founder and president of Sumaq Life LLC. Dr Hodges receives book royalties from Elsevier. Professional and scientific bodies have reimbursed him for travel costs related to presentation of research on pain, motor control, and exercise therapy at scientific conferences/ symposia. He has received fees for teaching practical courses on motor control training. He is also supported by a Senior Principal Research Fellowship from the National Health and Medical Research Council of Australia (APP1102905). The other authors certify that they have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the letter.

REFERENCES

- 1. Cholewicki J, Silfies SP, Shah RA, et al. Delayed trunk muscle reflex responses increase the risk of low back injuries. Spine (Phila Pa 1976). 2005;30:2614-2620. https://doi.org/10.1097/01. brs.0000188273.27463.bc
- 2. Granata KP, Slota GP, Wilson SE. Influence of fatigue in neuromuscular control of spinal stability. Hum Factors. 2004;46:81-91. https://doi. org/10.1518/hfes.46.1.81.30391
- 3. Reeves NP, Cholewicki J, van Dieën JH, Kawchuk G, Hodges PW. Are stability and instability relevant concepts for back pain? J Orthop Sports Phys Ther, 2019:49:415-424, https://doi. org/10.2519/jospt.2019.8144
- 4. Reeves NP, Luis A, Chan EC, Sal y Rosas VG,

- Tanaka ML. Assessing delay and lag in sagittal trunk control using a tracking task. J Biomech. 2018;73:33-39. https://doi.org/10.1016/j. jbiomech.2018.03.029
- 5. Rowley KM, Gordon J, Kulig K. Characterizing the balance-dexterity task as a concurrent bipedal task to investigate trunk control during dynamic balance. J Biomech. 2018;77:211-217. https://doi. org/10.1016/j.jbiomech.2018.07.014
- 6. Rowley KM, Smith JA, Kulig K. Reduced trunk coupling in persons with recurrent low back pain is associated with greater deep-tosuperficial trunk muscle activation ratios during the balance-dexterity task. J Orthop Sports Phys Ther. In press. https://doi.org/10.2519/ jospt.2019.8756

GO GREEN By Opting Out of the Print Journal

JOSPT subscribers and APTA members of the Orthopaedic and Sports Physical Therapy Sections can help the environment by "opting out" of receiving JOSPT in print each month as follows. If you are:

- A JOSPT subscriber: Email your request to jospt@jospt.org or call the JOSPT office toll-free at 1-877-766-3450 and provide your name and subscriber number.
- APTA Orthopaedic or Sports Section member: Go to http://www.apta.org/, log in, and select My Profile. Next click on Email Management/GoGreen. Toward the bottom of the list, you will find the **Publications** options and may opt out of receiving the print JOSPT. Please save this preference.

Subscribers and members alike will continue to have access to *JOSPT* online and can retrieve current and archived issues anytime and anywhere you have Internet access.

Patients as Partners in Research: It's the Right Thing to Do

JOLETTA BELTON. MSc

Endless Possibilities Initiative, Fraser, CO Retrain Pain Foundation, Mamaroneck, NY

ALISON HOENS, MSc, BScPT

Department of Physical Therapy, University of British Columbia, Vancouver, Canada Centre for Health Evaluation and Outcomes Sciences, University of British Columbia, Vancouver, Canada

ALEX SCOTT, PT, PhD

Department of Physical Therapy, University of British Columbia, Vancouver, Canada

CLARE L. ARDERN, PT, PhD

Editor-in-Chief Division of Physiotherapy, Karolinska Institute, Stockholm, Sweden

J Orthop Sports Phys Ther 2019;49(9):623-626. doi:10.2519/jospt.2019.0106

he health research landscape is changing, and it is time for the *Journal of Orthopaedic & Sports Physical Therapy* (*JOSPT*) community to "up our game" by fostering authentic opportunities for patient engagement in musculoskeletal research and practice.

In this editorial, we argue that successful patient engagement improves the quality of physical therapy research. Although authentic engagement has challenges, the benefits are well worth the investment of time and energy to overcome these challenges. We outline 3 steps JOSPT is taking to promote and support patient partnership in musculoskeletal research.

What Is Patient Partnership in Research?

Researchers have traditionally served as gatekeepers—researchers decide which questions to answer, which treatments to study, and how to measure treatment success. After analyzing and interpreting their measurements, researchers disseminate their findings through academic channels such as peer-reviewed journals and presentations at conferences. Often, the articles reside behind paywalls, and conferences have their doors firmly closed to patient participation.

The "researcher-as-gatekeeper" paradigm has generated a wealth of knowledge and has contributed to improved treatment in many conditions. However, there are risks with such a paradigm, including (1) pursuing questions that do not capture key aspects of the patient

experience, (2) measuring outcomes of limited relevance to patients, and (3) inadequate knowledge translation that prevents patients and clinicians from effectively applying research findings in real-world settings. When researchers partner with patients (and clinicians) to do research, these risks are reduced. "Patient-oriented research" must meet at least 1 of the criteria in TABLE 1.

The Canadian Institutes of Health Research Strategy for Patient-Oriented Research: Patient Engagement Framework (http://www.cihr-irsc.gc.ca/e/48413. html) and the International Association for Public Participation spectrum of public participation framework (FIGURE) are two frameworks that can be used to foster partnerships among researchers, patients, and clinicians. JOSPT aims for the "collaborate" level of engagement.

EDITORIAL

TABLE 1 CRITERIA FOR PATIENT-ORIENTED RESEARCH ⁶					
Condition	Description				
1	Patients (including relatives, family caregivers, and the public) are involved as research partners with multidisciplinary or transdisciplinary team members (including decision/policy makers, patients, and clinicians) along a continuum in addressing patient priorities or planning/conducting research (eg, formulation of the question; data collection/analysis; interpretation, diffusion, dissemination, and application of results), or both addressing patient priorities and planning/conducting research				
2	Studies aim to (a) address outcomes deemed important by patients; (b) have a direct impact on at least 1 of the following targets: patient health and experiences, health professionals' practice, or health care services and policies; or (c) achieve both objectives a and b				

INFORM	CONSULT	INVOLVE	COLLABORATE	EMPOWER
To provide the public with balanced and objective information to assist them in understanding the problem, alternatives, opportunities and/or solutions.	To obtain public feedback on analysis, alternatives and/or decisions.	To work directly with the public throughout the process to ensure that public concerns and aspirations are consistently understood and considered.	To partner with the public in each aspect of the decision including the development of alternatives and the identification of the preferred solution.	To place final decision making in the hands of the public.
We will keep you informed.	We will keep you informed, listen to and acknowledge concerns and aspirations, and provide feedback on how public input influenced the decision.	We will work with you to ensure that your concerns and aspirations are directly reflected in the alternatives developed and provide feedback on how public input influenced the decision.	We will look to you for advice and innovation in formulating solutions and incorporate your advice and recommendations into the decisions to the maximum extent possible.	We will implement what you decide.

FIGURE. The International Association for Public Participation spectrum of public participation framework. Patient engagement occurs along a spectrum from informing to empowering. Reprinted with kind permission from the International Association for Public Participation International Federation.

How Patient Partnerships Can Benefit Research

It is challenging to measure the impact of patient partnerships on a research program, and research on patient partnerships is in early stages.9 There is a benefit to participant recruitment and retention—the bane of many studies.1 There is also a growing list of conditions in which patients have alerted clinicians to core domains and to what should be considered (eg, fatigue associated with rheumatoid arthritis⁷).

During the Fifth International Scientific Tendinopathy Symposium, held in 2018 in Groningen, the Netherlands, health care practitioners (n = 28) and

patient partners (n = 32) collaborated to develop a consensus statement on persistent tendinopathy. After the first stage of the Delphi survey, only 36% of health care practitioners believed that psychological impact was an important domain of persistent tendinopathy. Seventy-seven percent of patients thought that psychological impact was important.

If the Delphi survey had not included patient partners, the psychological impact domain would have been dropped from consideration. After stage 2 (inperson discussion among health care practitioners and patient partners), the psychological impact domain achieved 88% consensus. The results were similar

for sports participation, which would not have been included as a core domain if not for guidance from patients. These are concrete examples of patients articulating what is important about their condition and partnering with researchers to ensure its inclusion in research.

Now Is the Right Time for Partnerships Between Researchers and Patients in Musculoskeletal Rehabilitation Research

Many participants in studies published in JOSPT are people living with pain who sacrifice their time to help future patients. In addition to being participants in research, people with lived experience bring valuable knowledge-contributing to a broader understanding of the treatments researchers study, improved knowledge translation, and more successful outcomes.

Rather than researchers informing patients and clinicians about a condition and instructing patients how to behave, engaging in a way that promotes sharing and understanding of a patient's unique, lived experience can mean that patients, clinicians, and researchers answer key clinical questions together. Leading biomedical journals (eg, the BMJ and CMAJ Open) have policies and initiatives to promote patient-oriented research. It is time for JOSPT to enter this arena.

Challenges When Building Patient Partnerships for Research

Because patient partnership is a relatively new approach to doing research,3 there is limited experience in "how" to do this well. Typical challenges faced by research teams new to this type of research partnership include the following.

- 1. Partnering with patients requires an investment of time, and researchers want to be confident that the outcomes are worth this investment. Fortunately, there are promising trends in patientpartner research, including higher recruitment and retention rates and greater intervention adherence.4
- 2. There is no single recipe for how to do patient-partner engagement well.

TABLE 2

SUCCESSFUL PATIENT-ENGAGEMENT APPROACHES FOR HEALTH RESEARCH^{2,5}

- 1. Engage patients as early as possible and continue engagement
- 2. Clearly define the patient-engagement plan: be clear on roles, duties, and expectations between patients and researchers
- 3. Provide orientation and education about research and patient engagement
- 4. Provide ongoing support, encouragement, and recognition for patient contributions
- 5. Facilitate mutual respect and valuing of patients' expertise based on knowledge gained through experiences
- 6. Ensure a trusting and positive environment by providing structural support
- 7. Include a plan for evaluating engagement

TABLE 3

SHARED CHARACTERISTICS OF SUCCESSFUL PATIENT ENGAGEMENT IN HEALTH RESEARCH⁸

- · Clear purpose, role, and structure for engaging patients
- Initiate and maintain partnerships between researchers and stakeholders
- · Take the time required to foster relationship building as the most critical component in establishing trust
- · Clear leadership from principal investigator and/or wider culture of involvement
- Promote the need for facilitation of cross-communication among all groups
- · Capture and facilitate patient perspectives across all phases of research
- Ensure meaningful patient influence on research by validating the need for respect and support for patients
- Ensure adequate training for researchers and patients
- · Share and promote research findings, including evaluation efforts

However, there are teams in Canada, the United Kingdom, and Australia researching preferred methods for how to recruit, orient, train, and work with patient partners, and subsequently to measure the effectiveness and outcomes of these partnerships. *JOSPT* authors can contribute to and help develop this field of research.

Overcoming these barriers will be best addressed by purposeful attention to and use of best practices in patient engagement in research (current best evidence and practice).

How JOSPT Plans to Support Authors

The JOSPT patient-partnership editorial series will (1) describe key frameworks

"It is our lives that are at stake, after all. Shouldn't we have a say? It is we who have to live with these conditions and experiences for which we are seeking care. We seek care because we cannot figure it out on our own. We need your expertise, your knowledge of the research, your clinical expertise. We also need for you to bring your own humanity to the table. To see us as fellow humans who are trying to make sense of things and find a way forward. That we will not be in your care forever. That even while we are in your care, we are largely living with these experiences and conditions on our own. You are in the best position to help us find that way forward with us. It can only be discovered together."

— Joletta Belton

and approaches for developing patient partnerships in research (TABLE 2), (2) share tips and resources for researchers considering patient partnership (TABLE 3), and (3) outline JOSPT's policy on patient partnership in research.

Call to Action: Next Steps for the JOSPT Community

JOSPT is taking concrete steps to promote and support patient partnership in musculoskeletal research.

- Requiring all new manuscript submissions from January 1, 2020 to include a statement about how (if at all) patients were involved in the research
- Welcoming Ms Joletta Belton as patient-partnership lead on the *Journal's* Editorial Board
- 3. Establishing a patient-partnership working group to connect with our community, ensuring we address the issues that matter to you

We invite readers and authors to contribute to the discussion on patient partnership in research. Connect via our social media channels (Twitter: @JOSPT; Facebook: @JOSPTOfficial) and share your ideas. We welcome your suggestions for future editorials in this series. How can this space best serve researchers, educators, and clinicians? How can it serve those who live with an injury/condition/disease/pain or other symptoms, and those who love or care for them?

REFERENCES

- Crocker JC, Ricci-Cabello I, Parker A, et al. Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis. *BMJ*. 2018;363:k4738. https://doi.org/10.1136/bmj. k4738
- Duffett L. Patient engagement: what partnering with patient in research is all about. *Thromb* Res. 2017;150:113-120. https://doi.org/10.1016/j. thromres.2016.10.029
- Fergusson D, Monfaredi Z, Pussegoda K, et al. The prevalence of patient engagement in published trials: a systematic review. Res Involv

EDITORIAL

- Engagem. 2018;4:17. https://doi.org/10.1186/s40900-018-0099-x
- Forsythe LP, Carman KL, Szydlowski V, et al. Patient engagement in research: early findings from the Patient-Centered Outcomes Research Institute. Health Aff (Millwood). 2019;38:359-367. https://doi.org/10.1377/hlthaff.2018.05067
- Hibbard JH, Greene J. What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs.
- Health Aff (Millwood). 2013;32:207-214. https://doi.org/10.1377/hlthaff.2012.1061
- Kaur N, Pluye P. Delineating and operationalizing the definition of patient-oriented research: a modified e-Delphi study. J Patient Cent Res Rev. 2019;6:7-16. https://doi.org/10.17294/ 2330-0698.1655
- Kirwan JR, Hewlett SE, Heiberg T, et al. Incorporating the patient perspective into outcome assessment in rheumatoid arthritis--progress at
- OMERACT 7. J Rheumatol. 2005;32:2250-2256.
- Manafo E, Petermann L, Mason-Lai P, Vandall-Walker V. Patient engagement in Canada: a scoping review of the 'how' and 'what' of patient engagement in health research. Health Res Policy Syst. 2018;16:5. https://doi.org/10.1186/s12961-018-0282-4
- Staley K. 'Is it worth doing?' Measuring the impact of patient and public involvement in research. Res Involv Engagem. 2015;1:6. https://doi.org/10.1186/s40900-015-0008-5

EARN CEUs With JOSPT's Read for Credit Program

JOSPT's Read for Credit (RFC) program invites readers to study and analyze selected JOSPT articles and successfully complete online exams about them for continuing education credit. To participate in the program:

- Go to www.jospt.org and click on Read for Credit in the top blue navigation bar that runs throughout the site.
- Log in to read and study an article and to pay for the exam by credit card.
- When ready, click Take Exam to answer the exam questions for that article.
- 4. Evaluate the RFC experience and receive a personalized certificate of continuing education credits.

The RFC program offers you 2 opportunities to pass the exam. You may review all of your answers—including your answers to the questions you missed. You receive **0.2 CEUs**, or 2 contact hours, for each exam passed.

JOSPT's website maintains a history of the exams you have taken and the credits and certificates you have been awarded in My CEUs and Your Exam Activity, located in the right rail of the Read for Credit page listing available exams.

JOOST F.A. EIJKENBOOM, MSc¹ • EVERLIEN R. TIMMER, BSc¹ • RIANNE A. VAN DER HEIJDEN, PhD, MD²

JANNEKE L.M. DE KANTER, PhD, MD² • EDWIN H.G. OEI, PhD, MD²

SITA M.A. BIERMA-ZEINSTRA, PhD¹ • MARIENKE VAN MIDDELKOOP, PhD¹

Association Between Self-reported Measures, Physical Examination, and Early Magnetic Resonance Imaging Signs of Osteoarthritis in Patients With Patellofemoral Pain

atellofemoral pain (PFP) is a highly prevalent disorder. Of patients who visit a general practitioner with knee pain, 12% are diagnosed with PFP,³⁴ which has a peak incidence during adolescence. Patellofemoral pain is described as pain around or behind the patella associated with prolonged sitting, squatting, kneeling,

- BACKGROUND: Structural abnormalities associated with osteoarthritis (OA) are found in some patients with patellofemoral pain (PFP).
- OBJECTIVES: To investigate the association between early signs of OA on magnetic resonance imaging (MRI) and characteristics from selfreported measures and physical examination in patients with PFP.
- **METHODS:** This exploratory study included data from patients with PFP from a previously published cross-sectional case-control study (n = 64; 55% female; mean ± SD age, 23.4 ± 7.0 years). Structural OA features (osteophytes, bone marrow lesions, cartilage defects, Hoffa synovitis, patellar tendon abnormalities) and quantitative T2 measurements of cartilage composition were extracted from MRI. Associations between characteristics from self-reported measures (pain at rest, pain during stair walking, knee function, duration of complaints, hours of sports participation each week), physical examination (crepitus, quadriceps strength), and early MRI signs of OA were assessed.
- **RESULTS:** Symptom duration was associated with bone marrow lesions in the patella (odds ratio [OR] = 1.1; 95% confidence interval [CI]: 1.0, 1.2). Sports participation (hours per week) was inversely associated with patellar tendon abnormalities on MRI (OR = 0.8; 95% CI: 0.6, 1.0). Crepitus and bilateral nature of the complaints were associated with minor patellar cartilage defects (OR = 12.0; 95% CI: 2.3, 63.6 and OR = 7.6; 95% CI: 1.1, 53.8, respectively). There were no significant associations between clinical characteristics and cartilage T2 relaxation time.
- CONCLUSION: Presence of crepitus, bilateral complaints, a long PFP symptom duration, and reduced weekly sport participation were associated with early signs of OA in a young PFP population.
- LEVEL OF EVIDENCE: Etiology, level 2c.
 J Orthop Sports Phys Ther 2019;49(9):634-639.
 Epub 10 Jul 2019. doi:10.2519/jospt.2019.8889
- **KEY WORDS:** cartilage composition, knee, MRI, patellofemoral joint, structural OA features

and stair climbing.⁵ Contrary to earlier beliefs, PFP is not self-limiting and carries a personal and societal burden.²² Multiple studies have been conducted to obtain more insight into this multifactorial condition, but the exact etiology is still unknown.

It has been proposed that PFP is a risk factor for the development of patellofemoral osteoarthritis (OA).⁴ Therefore, changes in bone and cartilage associated with early OA, such as osteophytes, bone marrow lesions, Hoffa synovitis, and deteriorating cartilage composition, have been proposed as potential pathophysiological factors of PFP.^{5,10,20} T2 mapping can quantitatively measure the amount of water molecules in articular cartilage, and has been accepted as an early sign of OA^{6,27} and could therefore play a role in understanding PFP pathophysiology.

Early signs of OA are prevalent in patients with PFP.²⁹ However, these abnormalities were also seen in the healthy control population.²⁹ It is unclear whether the abnormalities seen on magnetic resonance imaging (MRI) in patients

Department of General Practice, Erasmus University Medical Center, Rotterdam, the Netherlands. ²Department of Radiology and Nuclear Medicine, Erasmus University Medical Center, Rotterdam, the Netherlands. The present study was financially supported by the Stichting Annafonds|NOREF and Erasmus University Rotterdam. The Medical Ethics Committee of the Erasmus University Medical Center approved this study (protocol MEC-2012-342). The authors certify that they have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the article. Address correspondence to Joost F.A. Eijkenboom, Department of General Practice, Erasmus University Medical Center, PO Box 2040, 3000 CA Rotterdam, the Netherlands. E-mail: j.eijkenboom@erasmusmc.nl © Copyright ©2019 Journal of Orthopaedic & Sports Physical Therapy

with PFP are related to clinical presentation and symptoms. It is important to investigate this potential association, because patients with early OA features may be prone to developing definitive OA in the patellofemoral joint at a later age. The identification of this subgroup by self-reported measures and physical examination could have clinical value in the education and early treatment of patients, and in preventing the development of OA later in life.

Several factors, such as quadriceps weakness,16 crepitation,17 duration of complaints,1 and severity of knee pain,2 have previously been associated with a poor prognosis of PFP. We hypothesized that risk factors from self-reported measures and physical examination may also be associated with the early signs of OA seen in patients with PFP, and consequently with a poor prognosis of PFP. Although imaging outcome measures are not included in the routine clinical work-up for PFP³³ and early signs of OA on MRI are highly prevalent (90%) in patients without knee pathologies, 12 the identification of patient and clinical characteristics potentially associated with early signs of OA on MRI could help to identify younger individuals who are at risk of developing OA. The aim of this exploratory study was to investigate whether clinical characteristics from selfreported measures and physical examination were associated with early signs of OA seen on MRI in young patients with PFP.

METHODS

Study Population

ATA FROM PATIENTS WITH PFP COLlected in a previously conducted cross-sectional case-control study were used for the current study.²⁹ Patients were recruited by physical therapists, sport physicians, and general practitioners. The diagnosis of PFP was based on presence of at least 3 of the following symptoms: crepitus or pain while stair climbing, squatting, running, cycling, or sitting for a prolonged period with the knee flexed.²⁹ Patients between 14 and 40 years of age were included, with a minimum symptom duration of 2 months and a maximum of 2 years,29 to improve generalizability.32 Patients with previously diagnosed knee pathologies, such as clinically diagnosed Osgood-Schlatter disease and patellar tendinopathy, surgery or injury, contraindication to MRI with contrast administration (not used in the current study), and insufficient knowledge of the Dutch language were excluded. The Medical Ethics Committee of the Erasmus University Medical Center (protocol MEC-2012-342) approved this study, informed consent was accordingly obtained from all participants, and the rights of participants were protected before measurements took place.

Measurements

Clinical measurements included physical examination and self-reported measures assessed by questionnaires. The questionnaires included questions on demographics (sex, height, weight, and age), sports participation (average hours of sports participation per week at the time of inclusion), duration of complaints, and pain severity during activity in the past week (numeric rating scale for pain¹³). Self-reported physical functioning was assessed with the Anterior Knee Pain Scale,15 and bilateral complaints were recorded (yes/no). The stairs subscale of the Anterior Knee Pain Scale was dichotomized to make interpretation easier (difficulty/no difficulty). "Severe pain" during stair walking was defined as "pain both when ascending and descending" or "unable," while "no or slight pain" was defined as "no difficulty" or "slight pain when descending." The standardized physical examination included presence of crepitus during squatting (yes/no), painful palpation of the medial patellar compartment (yes/no), Clarke's compression test,21 and measurements of quadriceps strength.31 Presence of crepitus was defined as an audible grinding noise and/or palpable vibrations in the knee, detected by the hand of the investigator resting on the patella of the participant during loaded active flexion or extension of the knee. Quadriceps strength was measured 3 times using a handheld dynamometer³¹ (microFET2; Hoggan Scientific, LLC, Salt Lake City, UT). The 2 highest values were used to determine the mean quadriceps strength per kilogram of body weight. The affected knee, or randomly chosen knee when both knees were equally painful, was used for all questionnaires and measurements in this study.

A 3-T MRI scanner (Discovery MR750; General Electric Company, Boston, MA) with a dedicated 8-channel knee coil (Koninklijke Philips NV, Amsterdam, the Netherlands) was used with a protocol that included the following pulse sequences: sagittal, axial, and coronal fast spinecho, proton density-weighted sequences with a slice thickness of 3 mm, and sagittal and axial T2-weighted sequences with fat suppression and a slice thickness of 3 mm. The full MRI protocol can be found in the APPENDIX (available at www.jospt.org).

MRI Analysis

The semi-quantitative Magnetic Resonance Imaging Osteoarthritis Knee Score (MOAKS14) tool was used to score OA features in the patellofemoral joint.³⁰ The MOAKS is a validated tool developed to study OA. Additional patellofemoral joint features, possibly more applicable in this young population, were added: minor cartilage defects (defined as high signal intensity, fraying or fissuring or hypertrophy of the cartilage), patellar tendon abnormalities (defined as thickening or high signal of the patellar tendon), and Hoffa synovitis (defined as high-signal superolateral or moderate to severe edema of the Hoffa fat pad). These features were scored by a blinded senior resident in radiology with musculoskeletal subspecialization and later dichotomized as 1 (present) and 0 (not present) to reduce the large numbers of MRI features.²⁹ All findings were confirmed by an experienced, blinded musculoskeletal radiologist. The 5 most prevalent and relevant features with regard to PFP were used

for the analysis (patellar osteophytes, bone marrow lesions in the patella, patellar tendon abnormalities [defined as tendon thickening or high-signal tendon on MRI], minor patellar cartilage defects [high signal, hypertrophy, and fraying], and Hoffa synovitis).29 The T2 mapping MRI sequence was used to quantify cartilage composition, with higher T2 relaxation times indicating a deteriorated biochemical cartilage composition.19 Weighted mean relaxation times were calculated separately for the anterior femur cartilage and patellar cartilage. Segmentations were performed by a blinded experienced observer.30

Statistical Analysis

TABLE 1

Statistical analyses were performed using SPSS Version 21 (IBM Corporation, Armonk, NY). Patient characteristics and prevalence of early signs of OA were described using descriptive statistics. Associations between self-reported measures, features from physical examination, and early signs of OA on MRI were analyzed using linear (T2 relaxation times) and logistic regression (MOAKS features) models, adjusted for age, sex, and body mass index. The linear regression results were presented as unstandardized regression coefficients (beta) and the logistic regression results were presented as odds ratios (ORs), both with 95% confidence intervals (CIs). Missing values were handled by performing complete case analysis.

RESULTS

CHARACTERISTICS OF PATIENTS WITH

 $\overline{\text{PATELLOFEMORAL PAIN}}$ (N = 64)

IXTY-FOUR PATIENTS WITH PFP were included between January 2013 and September 2014 (TABLE 1). The mean age was 23.4 years, the mean body mass index was 23.6 kg/m², and 35 (55%) of the patients were female. T2 relaxation times were available for 63 participants (acquisition failed in 1 patient). Structural abnormalities on MRI were scored in all participants.

Osteophytes on the patella were present in 70% of patients, and bone marrow lesions were seen in 53% of patients. Hoffa synovitis was present in 57.8% of the patients. Less prevalent features included abnormalities of the patellar tendon (38%) and minor patellar cartilage defects (23%).

TABLE 2 shows the associations between clinical characteristics and structural abnormalities on MRI. A longer duration of complaints was associated with the presence of bone marrow lesions in the patella (OR = 1.1; 95% CI: 1.0, 1.2). Additionally, both the presence of crepitus (OR = 12.0; 95% CI: 2.3, 63.6) and the bilateral nature of the complaints (OR = 7.6; 95% CI: 1.1, 53.8) were associated with minor cartilage defects in the patella. The pretest probability for minor cartilage defects was 23.4%, while the posttest probability after presence of crepitus was 44.8% for minor cartilage defects, and the posttest probability after bilateral nature of complaints was 27.3% for minor cartilage defects. Finally, number of hours of sports participation per week was inversely associated with patellar tendon abnormalities (OR = 0.8; 95% CI: 0.6, 1.0).

There were no associations between any of the clinical characteristics and T2 relaxation times (TABLE 3).

DISCUSSION

LONGER SYMPTOM DURATION OF PFP was associated with the prevalence of bone marrow lesions in the patella. There was an association between both crepitus and bilateral complaints and the prevalence of minor cartilage defects on the patella. However, these associations had large CIs that may be caused by the relatively small sample size. Biochemical cartilage composition was not associated with any of the clinical characteristics.

Measure	Value*
Sex (female), n (%)	35 (54.7)
Age, y	23.4 ± 7.0
Body mass index, kg/m ²	23.6 ± 3.8
Pain during activity (NRS, 0-10)	6.6 ± 2.2
Anterior Knee Pain Scale (0-100)	66.3 ± 11.6
Severe pain or unable to walk stairs, n (%)	41 (64.1)
Sports participants at study inclusion, n (%)	38 (59.4)
Hours of sports participation per week	2.4 ± 2.4
Presence of crepitus, n (%)	29 (45.3)
Positive Clarke compression test, n (%)	14 (21.9)
Painful palpation: medial patellar facet, n (%)	31 (48.4)
Quadriceps strength, N/kg	3.67 ± 1.23
Structural abnormalities, n (%)	
Osteophytes: patella	45 (70.3)
BML: patella	34 (53.1)
Minor cartilage defects: patella	15 (23.4)
Patellar tendon abnormalities	24 (37.5)
Hoffa synovitis	37 (57.8)
Cartilage composition, ms [†]	
T2 relaxation time: femur cartilage	36.6 ± 2.5
T2 relaxation time: patellar cartilage	33.2 ± 2.8

Abbreviations: BML, bone marrow lesion; NRS, numeric rating scale.

*Values are mean \pm SD unless otherwise indicated.

 $^{\dagger}n = 63.$

TABLE 2

Association Between Structural Abnormalities Seen on Magnetic Resonance Imaging and Clinical Characteristics*

			Minor Cartilage Defects:	Patellar Tendon	
Clinical Measures	Osteophytes: Patella	BML: Patella	Patella	Abnormalities	Hoffa Synovitis
Pain and function					
Pain during activity (NRS, 0-10)	1.04 (0.79, 1.36)	1.13 (0.88, 1.44)	1.01 (0.73, 1.38)	1.04 (0.81, 1.34)	1.05 (0.79, 1.38)
Pain during walking stairs	0.33 (0.08, 1.29)	0.86 (0.29, 2.54)	0.87 (0.24, 3.19)	0.45 (0.15, 1.37)	0.69 (0.21, 2.22)
Knee function (AKPS, 0-100)	1.04 (0.97, 1.10)	0.96 (0.91, 1.02)	1.02 (0.95, 1.09)	0.99 (0.94, 1.04)	1.01 (0.95, 1.06)
Clinical characteristics					
Duration of complaints, mo	0.96 (0.88, 1.04)	1.10 (1.00, 1.21)†	1.06 (0.96, 1.17)	1.06 (0.98, 1.15)	0.95 (0.87, 1.04)
Bilateral complaints	1.22 (0.34, 4.39)	1.75 (0.52, 5.88)	7.62 (1.08, 53.75) [†]	0.29 (0.08, 1.06)	1.94 (0.53, 7.06)
Presence of crepitus	1.74 (0.52, 5.83)	1.36 (0.47, 3.94)	11.95 (2.25, 63.61)†	1.20 (0.41, 3.54)	0.38 (0.12, 1.26)
Sports participation, h/wk	1.16 (0.90, 1.50)	0.85 (0.69, 1.06)	1.07 (0.82, 1.39)	0.75 (0.59, 0.97)†	0.89 (0.71, 1.12)
Quadriceps strength, N/kg	1.08 (0.62, 1.88)	0.98 (0.61, 1.60)	1.17 (0.63, 2.16)	0.63 (0.36, 1.10)	1.02 (0.61, 1.70)

Abbreviations: AKPS, Anterior Knee Pain Scale; BML, bone marrow lesion; NRS, numeric rating scale.

Severity of pain and loss of function were not associated with early signs of OA in young patients with PFP. Even though there is a relatively high prevalence of early signs of OA, these signs do not seem to be responsible for the variation in pain severity, functional impairment, or pain during stair walking. This is in line with earlier findings in OA research that show that functional impairment and pain severity are rarely associated with synovitis and bone marrow lesions in patients with OA. However, variation in pain severity and functional impairment have both been associated with both synovitis and bone marrow lesions in patients with OA.³⁵ It would be interesting to examine these associations in a longitudinal study following young patients with PFP and their possible progression to OA.

Quantitative MRI measures for changes in cartilage composition have recently been proposed as objective end points for early OA research, 11 because changes in cartilage composition are present in the early OA disease process. 18 One of these measures, T2 relaxation time, has been suggested to be a sensitive imaging marker for quantitative monitoring of macromolecules in early OA. 23 T2 relaxation times have been reported to be significantly higher in pa-

TABLE 3

The Association Between Biochemical Cartilage Composition and Clinical Characteristics (n = 63)*

Clinical Measures	T2 Relaxation Time: Anterior Femur, ms	T2 Relaxation Time: Patella, ms
Pain and function		
Pain during activity (NRS, 0-10)	-0.11 (-0.40, 0.18)	-0.03 (-0.38, 0.33)
Pain during stair walking	-0.46 (-1.72, 0.80)	0.22 (-1.34, 1.79)
Knee function (AKPS, 0-100)	0.02 (-0.04, 0.08)	0.05 (-0.03, 0.12)
Clinical characteristics		
Duration of complaints, mo	0.02 (-0.07, 0.11)	0.04 (-0.07, 0.15)
Bilateral complaints	0.37 (-1.00, 1.75)	-0.11 (-1.81, 1.59)
Presence of crepitus	0.67 (-0.56, 1.91)	0.72 (-0.80, 2.25)
Sports participation, h/wk	-0.13 (-0.37, 0.12)	-0.14 (-0.32, 0.30)
Quadriceps strength, N/kg	-0.27 (-0.84, 0.31)	-0.41 (-1.11, 0.30)

Abbreviations: AKPS, Anterior Knee Pain Scale; NRS, numeric rating scale.

tients with early OA compared to healthy controls.²⁷ Nevertheless, we previously showed that no difference was present in composition of patellofemoral cartilage between patients with PFP and healthy control participants.³⁰ In the current study, there was no association between cartilage composition and characteristics from self-reported pain and function and physical examination. As biochemical changes in cartilage are hypothesized to precede cartilage damage in OA, and a strong association was found between

minor cartilage defects and crepitus, we expected to find an association between T2 measures and crepitus. However, post hoc analysis revealed that T2 measures were not associated with minor cartilage defects.

There was an association between the presence of crepitus and minor cartilage defects on the patella. These findings are in line with the previously described strong association between the presence of crepitus and cartilage defects in patients with patellofemoral OA.²⁶ Crepitus has

^{*}Values are odds ratio (95% confidence interval). All analyses were adjusted for body mass index, age, and sex.

[†]Statistically significant (P<.05).

^{*}Values are unstandardized regression coefficient (95% confidence interval). All analyses were adjusted for body mass index, age, and sex.

been associated with various other knee abnormalities (ie, osteophytes, meniscal damage, cruciate pathology, and medial collateral ligament pathology) on both X-ray and MRI in people with knee pain.³ Because the prevalence of crepitus can be easily noted, it could be a convenient first indication of the onset of various radiological abnormalities within the knee. However, in our young population, the risk of such abnormalities for the individual patient with crepitus was still below 50%.

Bone marrow lesions worsen patient prognosis in both inflammatory and noninflammatory musculoskeletal conditions.^{7,28} We found a weak association between the presence of bone marrow lesions in the patella and a longer duration of complaints. This seems to be in line with Lankhorst et al,17 who found that a longer duration of complaints was associated with a poor prognosis for patients with PFP. The size and prevalence of bone marrow lesions may be associated with progression of disease⁹ in addition to cartilage loss,24 risk of total joint replacement,25 and pain8 in patients with OA. Our results imply that bone marrow lesions may also play a role in prognosis in patients with PFP.

Strengths and Limitations

We combined novel MRI techniques in a relatively large and young population with PFP, the findings of which add great value to the current literature. However, a high number of statistical tests were used in this group of patients with PFP, which increases the chance of false-positive findings. Nonetheless, when applying a Bonferroni correction for multiple testing, our strongest association (crepitus and minor cartilage defects) had a large effect size. To limit the number of statistical tests, we analyzed only the 5 most prevalent and relevant structural abnormalities. This led to the exclusion for analysis of structural abnormalities in a hypothetically important subregion in PFP: the trochlea.29 However, post hoc analysis showed no significant associations between clinical characteristics and symptoms and the most prevalent trochlear feature (osteophytes, n = 12).

Because structural abnormalities of the trochlea could not be taken into account due to their low prevalence, these outcomes are only applicable to individuals with patellar abnormalities. Only patients with PFP and a symptom duration between 2 and 24 months were included, and this may limit the generalizability of the findings to this specific group of patients. Due to the cross-sectional nature of our data, further research is needed to determine causality in the associations found.

CONCLUSION

AIN SEVERITY AND LOSS OF FUNCtion in PFP were not associated with early signs of OA. The presence of crepitus was strongly associated with minor cartilage defects on the patella.

•

EXEX POINTS

FINDINGS: Pain and loss of function in patients with patellofemoral pain were not associated with early signs of osteoarthritis seen on magnetic resonance imaging. Crepitus was strongly associated with minor cartilage defects on the patella in patients with patellofemoral pain.

IMPLICATIONS: The presence of crepitus may be an important clinical risk factor in patients with patellofemoral pain, indicating early cartilage damage.

CAUTION: A large number of statistical tests were used in our study, potentially leading to an overestimation of the number of

REFERENCES

statistically significant associations.

- Collins NJ, Bierma-Zeinstra SM, Crossley KM, van Linschoten RL, Vicenzino B, van Middelkoop M. Prognostic factors for patellofemoral pain: a multicentre observational analysis. Br J Sports Med. 2013;47:227-233. https://doi.org/10.1136/ bjsports-2012-091696
- Collins NJ, Crossley KM, Darnell R, Vicenzino B. Predictors of short and long term outcome in patellofemoral pain syndrome: a prospective longitudinal study. BMC Musculoskelet Disord. 2010;11:11. https://doi.

- org/10.1186/1471-2474-11-11
- Crema MD, Guermazi A, Sayre EC, et al. The association of magnetic resonance imaging (MRI)-detected structural pathology of the knee with crepitus in a population-based cohort with knee pain: the MoDEKO study. Osteoarthritis Cartilage. 2011;19:1429-1432. https://doi. org/10.1016/j.joca.2011.09.003
- **4.** Crossley KM. Is patellofemoral osteoarthritis a common sequela of patellofemoral pain? *Br J Sports Med*. 2014;48:409-410. https://doi.org/10.1136/bjsports-2014-093445
- 5. Crossley KM, Stefanik JJ, Selfe J, et al. 2016 patellofemoral pain consensus statement from the 4th International Patellofemoral Pain Research Retreat, Manchester. Part 1: terminology, definitions, clinical examination, natural history, patellofemoral osteoarthritis and patient-reported outcome measures. Br J Sports Med. 2016;50:839-843. https://doi.org/10.1136/bjsports-2016-096384
- 6. Dunn TC, Lu Y, Jin H, Ries MD, Majumdar S. T2 relaxation time of cartilage at MR imaging: comparison with severity of knee osteoarthritis. *Radiology*. 2004;232:592-598. https://doi. org/10.1148/radiol.2322030976
- Eriksen EF, Ringe JD. Bone marrow lesions: a universal bone response to injury? Rheumatol Int. 2012;32:575-584. https://doi.org/10.1007/ s00296-011-2141-2
- 8. Felson DT, Chaisson CE, Hill CL, et al. The association of bone marrow lesions with pain in knee osteoarthritis. *Ann Intern Med*. 2001;134:541-549. https://doi.org/10.7326/0003-4819-134-7-200104030-00007
- Felson DT, McLaughlin S, Goggins J, et al. Bone marrow edema and its relation to progression of knee osteoarthritis. Ann Intern Med. 2003;139:330-336. https:// doi.org/10.7326/0003-4819-139-5_part_1-200309020-00008
- Fulkerson JP. The etiology of patellofemoral pain in young, active patients: a prospective study. Clin Orthop Relat Res. 1983:129-133.
- Guermazi A, Alizai H, Crema MD, Trattnig S, Regatte RR, Roemer FW. Compositional MRI techniques for evaluation of cartilage degeneration in osteoarthritis. Osteoarthritis Cartilage. 2015;23:1639-1653. https://doi. org/10.1016/j.joca.2015.05.026
- 12. Guermazi A, Niu J, Hayashi D, et al. Prevalence of abnormalities in knees detected by MRI in adults without knee osteoarthritis: population based observational study (Framingham Osteoarthritis Study). BMJ. 2012;345:e5339. https://doi.org/ 10.1136/bmj.e5339
- 13. Hawker GA, Mian S, Kendzerska T, French M. Measures of adult pain: Visual Analog Scale for Pain (VAS Pain), Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Short-Form McGill Pain Questionnaire (SF-MPQ), Chronic Pain Grade Scale (CPGS), Short Form-36 Bodily Pain Scale (SF-36 BPS), and Measure of Intermittent and Constant Osteoarthritis Pain

- (ICOAP). Arthritis Care Res (Hoboken). 2011;63 suppl 11:S240-S252. https://doi.org/10.1002/ acr.20543
- 14. Hunter DJ, Guermazi A, Lo GH, et al. Evolution of semi-quantitative whole joint assessment of knee OA: MOAKS (MRI Osteoarthritis Knee Score). Osteoarthritis Cartilage. 2011;19:990-1002. https://doi.org/10.1016/j.joca.2011.05.004
- 15. Kujala UM, Jaakkola LH, Koskinen SK, Taimela S, Hurme M, Nelimarkka O. Scoring of patellofemoral disorders. *Arthroscopy*. 1993;9:159-163. https://doi.org/10.1016/ S0749-8063(05)80366-4
- Lankhorst NE, Bierma-Zeinstra SM, van Middelkoop M. Factors associated with patellofemoral pain syndrome: a systematic review. Br J Sports Med. 2013;47:193-206. https://doi.org/10.1136/bjsports-2011-090369
- 17. Lankhorst NE, van Middelkoop M, Crossley KM, et al. Factors that predict a poor outcome 5–8 years after the diagnosis of patellofemoral pain: a multicentre observational analysis. *Br J Sports Med*. 2016;50:881-886. https://doi.org/10.1136/bjsports-2015-094664
- Lorenzo P, Bayliss MT, Heinegård D. Altered patterns and synthesis of extracellular matrix macromolecules in early osteoarthritis. *Matrix Biol*. 2004;23:381-391. https://doi.org/10.1016/j.matbio.2004.07.007
- Matzat SJ, van Tiel J, Gold GE, Oei EH. Quantitative MRI techniques of cartilage composition. Quant Imaging Med Surg. 2013;3:162-174.
- McConnell J. Running injuries: the infrapatellar fat pad and plica injuries. *Phys Med Rehabil Clin N Am*. 2016;27:79-89. https://doi.org/10.1016/j. pmr.2015.08.009
- Nijs J, Van Geel C, Van der auwera C, Van de Velde B. Diagnostic value of five clinical tests in patellofemoral pain syndrome. *Man Ther*. 2006;11:69-77. https://doi.org/10.1016/j.math.2005.04.002

- 22. Rathleff MS, Rathleff CR, Olesen JL, Rasmussen S, Roos EM. Is knee pain during adolescence a self-limiting condition? Prognosis of patellofemoral pain and other types of knee pain. Am J Sports Med. 2016;44:1165-1171. https://doi.org/10.1177/0363546515622456
- 23. Regatte RR, Akella SV, Lonner JH, Kneeland JB, Reddy R. T_{1p} relaxation mapping in human osteoarthritis (OA) cartilage: comparison of T_{1p} with T₂. J Magn Reson Imaging. 2006;23:547-553. https://doi.org/10.1002/jmri.20536
- 24. Roemer FW, Guermazi A, Javaid MK, et al. Change in MRI-detected subchondral bone marrow lesions is associated with cartilage loss: the MOST Study. A longitudinal multicentre study of knee osteoarthritis. Ann Rheum Dis. 2009;68:1461-1465. https://doi.org/10.1136/ ard.2008.096834
- Scher C, Craig J, Nelson F. Bone marrow edema in the knee in osteoarthrosis and association with total knee arthroplasty within a three-year follow-up. Skeletal Radiol. 2008;37:609-617. https://doi.org/10.1007/s00256-008-0504-x
- 26. Schiphof D, van Middelkoop M, de Klerk BM, et al. Crepitus is a first indication of patellofemoral osteoarthritis (and not of tibiofemoral osteoarthritis). Osteoarthritis Cartilage. 2014;22:631-638. https://doi.org/10.1016/ j.joca.2014.02.008
- 27. Stahl R, Luke A, Li X, et al. T1rho, T₂ and focal knee cartilage abnormalities in physically active and sedentary healthy subjects versus early OA patients—a 3.0-Tesla MRI study. Eur Radiol. 2009;19:132-143. https://doi.org/10.1007/s00330-008-1107-6
- Starr AM, Wessely MA, Albastaki U, Pierre-Jerome C, Kettner NW. Bone marrow edema: pathophysiology, differential diagnosis, and imaging. Acta Radiol. 2008;49:771-786. https:// doi.org/10.1080/02841850802161023
- **29.** van der Heijden RA, de Kanter JL, Bierma-Zeinstra SM, et al. Structural abnormalities on

- magnetic resonance imaging in patients with patellofemoral pain: a cross-sectional case-control study. *Am J Sports Med.* 2016;44:2339-2346. https://doi.org/10.1177/0363546516646107
- 30. van der Heijden RA, Oei EH, Bron EE, et al. No difference on quantitative magnetic resonance imaging in patellofemoral cartilage composition between patients with patellofemoral pain and healthy controls. Am J Sports Med. 2016;44:1172-1178. https://doi.org/10.1177/0363546516632507
- 31. van der Heijden RA, Vollebregt T, Bierma-Zeinstra SM, van Middelkoop M. Strength and pain threshold handheld dynamometry test reliability in patellofemoral pain. Int J Sports Med. 2015;36:1201-1205. https://doi. org/10.1055/s-0035-1555855
- 32. van Linschoten R, van Middelkoop M, Berger MY, et al. Supervised exercise therapy versus usual care for patellofemoral pain syndrome: an open label randomised controlled trial. BMJ. 2009;339:b4074. https://doi.org/10.1136/bmj. b4074
- 33. Wang X, Oo WM, Linklater JM. What is the role of imaging in the clinical diagnosis of osteoarthritis and disease management? *Rheumatology*. 2018;57:iv51-iv60. https://doi.org/10.1093/ rheumatology/kex501
- 34. Wood L, Muller S, Peat G. The epidemiology of patellofemoral disorders in adulthood: a review of routine general practice morbidity recording. *Prim Health Care Res Dev.* 2011;12:157-164. https://doi.org/10.1017/S1463423610000460
- Zhang Y, Nevitt M, Niu J, et al. Fluctuation of knee pain and changes in bone marrow lesions, effusions, and synovitis on magnetic resonance imaging. Arthritis Rheum. 2011;63:691-699. https://doi.org/10.1002/art.30148



FIND Author Instructions & Tools on the Journal's Website

JOSPT's instructions to authors are available at www.jospt.org by clicking Complete Author Instructions in the right-hand Author Center widget on the home page, or by visiting the Info Center for Authors, located in the site's top navigation bar. The Journal's editors have assembled a list of useful tools and links for authors as well as reviewers.

[RESEARCH REPORT]

APPENDIX

MAGNETIC RESONANCE IMAGING PROTOCOL

Parameters	3-D SPGR	T2 Mapping
Plane	Sagittal	Sagittal
Imaging mode	3-D	3-D
Sequence	SPGR	FSE
Matrix: frequency	512	288
Matrix: phase	512	192
Number of slices	216	36
Field of view, mm	150	150
Slice thickness/gap, mm/mm	0.5/0.0	3.0/0.0
Echo time, ms	5.4	3/13/27/40/68
Flip angle, deg	12	90
Repetition time, ms	17	1263
Number of excitations	0.75	1
Fat saturated	Yes and no	Yes
Acquisition time, min	5:37	9:41

MUSCULOSKELETAL IMAGING



FIGURE 1. Lateral radiograph of the right lower leg demonstrating an area of focal bone formation within the soft tissues (arrow). The cortical margins of the tibia and fibula are intact



FIGURE 2. Coronal-view computed tomography image of the right lower leg demonstrating heterotopic ossification in the right soleus muscle (arrow). This courses along the myotendinous iunction of the muscle.

Nonsurgical Management of Heterotopic Ossification in a Runner

NADIA ARAIINEJAD JONES, DPT, SCS, Drayer Physical Therapy Institute, Tuscaloosa, AL. BRETT C. BENTLEY, MD, CAQSM, The University of Alabama, Tuscaloosa, AL. LANDON WAHL, DPT, OCS, Drayer Physical Therapy Institute, Somerset, PA.

51-YEAR-OLD MAN WAS REFERRED to physical therapy with right calf and anterior lateral lower-leg pain that had begun 3 weeks prior, after he had increased his running distance to train for a 10-km race. He also reported a calf strain while running 1 year prior, which resolved with rest. Radiographs ordered by his physician identified calcific changes within the mid-posterior lower leg (FIGURE 1). Computed tomography was ordered to further characterize the lesion (FIGURE 2) and identified heterotopic ossification in the right soleus. Patients with persistent symptoms from heterotopic ossification are typically referred to surgery for excision of ectopic bone.2 The patient understood that if he did not respond to nonsurgical care, he would be referred for surgical consultation.

Initial evaluation revealed hypertrophy of the right anterior tibialis, decreased ankle dorsiflexion range of motion, and decreased talocrural joint mobility. Instrument-assisted soft tissue mobilization and stretching to the anterior tibialis were coupled with talocrural dorsiflexion mobilizations, which immediately reduced the patient's anterior lower-leg pain with heel strike and right forward step-up.1 The patient refrained from running for 3 weeks and had complete resolution of pain. At that point, a running assessment demonstrated a right hip drop and overpronation during the stance phase of running. Dynamic single-leg gluteal-strengthening exercises were given to improve hip stability and power. After a total of 5 weeks of physical therapy, including instrument-assisted soft tissue mobilization, mobilizations, and progressive functional exercises, he could run 1.6 to 3.2 km pain free and was discharged with instruction to gradually increase distance. At 4-month follow-up, he reported that he was running 6.4 km pain free.

Heterotopic bone formation found on imaging may be disquieting but is indeterminate as the source of pain. Clinicians should take into consideration that findings on images may be incidental. Rest from running and physical therapy interventions directed at lower extremity impairments and compensatory movement patterns facilitated the resolution of the patient's symptoms without surgery. • J Orthop Sports Phys Ther 2019;49(9):676. doi:10.2519/jospt.2019.8491

References

^{1.} McPartland JM, Simons DG. Myofascial trigger points: translating molecular theory into manual therapy. J Man Manip Ther. 2006;14:232-239. https://doi.org/10.1179/106698106790819982

^{2.} Nauth A, Giles E, Potter BK, et al. Heterotopic ossification in orthopaedic trauma. J Orthop Trauma. 2012;26:684-688. https://doi.org/10.1097/BOT.0b013e3182724624

EVIDENCE IN PRACTICE

STEVEN J. KAMPER. PhD1

Interpreting Outcomes 3— Clinical Meaningfulness: Linking Evidence to Practice

J Orthop Sports Phys Ther 2019;49(9):677-678. doi:10.2519/jospt.2019.0705

o judge whether one treatment is more effective than another, simply knowing whether a difference exists is not enough. We need to know how big the difference is.⁴ One way of judging the size of the difference reported in a trial is to ask whether it is "clinically meaningful" (or clinically worthwhile): "The smallest change that is important to patients." A treatment is often said to

be "effective" and recommended for practice when the between-group difference in a study is larger than the clinically meaningful effect. But this simple idea hides some complexity.

Change and Difference (again)

A previous Evidence in Practice article explained the distinction between change in outcome within a group and difference between groups.³ The term *effect* should be reserved for between-group difference and avoided when talking about change within a group or person. When it comes to clinically meaningful effects, several terms are used, not always consistently, and often in ways that make interpretation difficult.

Minimally important change (MIC) and minimal clinically important change (MCIC) are fundamentally different from minimal clinically important difference (MCID). Researchers also use the term smallest worthwhile effect, which describes the same concept as MCID and refers to difference between groups. The problem is that these terms are often used interchangeably, which leads to confusion for readers.

Methods for Defining MCIC and MCID

Researchers generally express MCIC or MCID in units of a particular measure (eg, 2 points on a 0-to-10 pain scale) or as a proportion of change from baseline (eg, 30% improvement in Oswestry Disability Index score). Although the concept sounds simple, calculating a clinically meaningful difference is difficult. There are 4 common methods.

Proposal Researchers have proposed set definitions. A common example is Cohen's effect sizes: 0.2, 0.5, and 0.8 are thresholds for small, medium, and large effects, respectively. Cohen's effect sizes are multiples of the standard deviation. For example, the standard deviation on a 0-to-10 numeric pain-rating scale is usually approximately 2 points. So, an effect size of 0.5 would equate to about 1 point on a 0-to-10 scale. A problem with Cohen's effect sizes is that the thresholds are arbitrary: we do not know whether patients think differences of 0.2, 0.5, and 0.8 correspond to small, medium, and large effects. Moreover, "effect" sizes defined this way are quite often, but wrongly, applied to within-group changes, highlighting the problem of confused terminology.

Distribution-Based Methods Distribution-based methods used to define a MIC are based on the spread of the data in a study and dependent on the reliability of the measurement instrument.⁵ Distribution-based methods provide a threshold that is better interpreted as "minimum detectable change" rather than clinically important change. A change reported in a study that is smaller than the minimum detectable change might not be a real change at all, but rather "noise" due to error (poor reliability) in the measure. This method is not typically used to define meaningful differences.

Anchor-Based Methods Anchor-based methods compare changes on a measure over time to patients' ratings of their overall change during that period. Patients might be asked to rate their pain before treatment and again 2 weeks later. At the 2-week time point, patients are also asked how much their condition has improved over the past 2 weeks. Data from the patients will then be divided into 2 groups: those who consider themselves improved by a meaningful amount, and those who do not. The MIC is the mean change in pain scores for the group that considered themselves improved. This method is not typically used to define meaningful betweengroup differences.

*School of Public Health, University of Sydney, Camperdown, Australia; Centre for Pain, Health and Lifestyle, Australia. © Copyright ©2019 Journal of Orthopaedic & Sports Physical Therapy®

EVIDENCE IN PRACTICE

Benefit-Harm Trade-off Method This method involves interviews in which patients are presented with the costs, amount of time and effort, and risks of harms associated with an intervention. Patients are asked how much improvement they would need to experience to consider the intervention worthwhile. For example, "If you have to go to 6 sessions of physical therapy over 3 weeks, at \$80 per session, and do 20 minutes of exercise at home per day, how much improvement in pain would you need to make this worthwhile?"

Interpreting Meaningful Change and Difference

A major challenge to interpretation is that the proposal, distribution-based, and anchor-based methods calculate a minimally important *change*, not a minimally important *difference*. Despite this, MICs are often used to interpret the size of (between-group) effects. The exception is the benefit-harm trade-off method, which can be used to compare costs, time, and risks of harms of one treatment to those of another.¹ Unfortunately, the benefit-harm trade-off method has not been used very often to define clinically meaningful effect sizes in the orthopaedic and sports fields.

Most commonly, a MIC is attached to a measurement instrument (eg, the

MIC on a 0-to-10 numeric pain-rating scale is 2), and this number is used to interpret the between-group difference in randomized controlled trials. A problem is that interpretation does not account for important contextual factors. A MIC applied to a treatment with significant risks of harms, or an expensive treatment, should be larger than the MIC applied to a treatment without such risks and cost. Patients with more severe symptoms may require a larger change before they consider the change meaningful. Therefore, simply considering MIC or MCID as a feature of a measurement instrument is not advisable.

Determining What Is Clinically Meaningful in Practice

The methods used to calculate thresholds for clinically important change and clinically important difference are not ideal. However, clinicians who want to apply research evidence to practice need to appraise and interpret the size of treatment effects.

A sensible approach might be to be aware of the general range of estimates for clinically meaningful change or difference, and use the range as a coarse filter when reading research. You might ask yourself, "Is the effect size in a study in the ballpark of estimates for clinically

meaningful difference?" If no (ie, it is much smaller), then the intervention is probably not going to be useful to your patient. If yes, then the intervention might be an option. This probable effect size can be incorporated into a discussion with the patient that includes the costs, treatment period, patient expectations, and potential harms of treatment options to lead to a shared treatment decision.

•

REFERENCES

- Barrett B, Brown R, Mundt M, et al. Using benefit harm tradeoffs to estimate sufficiently important difference: the case of the common cold. *Med Decis Making*. 2005;25:47-55. https://doi. org/10.1177/0272989X04273147
- Huff D. How to Lie With Statistics. New York, NY: Norton; 1954.
- Kamper SJ. Interpreting outcomes 1—change and difference: linking evidence to practice. J Orthop Sports Phys Ther. 2019;49:357-358. https://doi.org/ 10.2519/jospt.2019.0703
- Kamper SJ. Interpreting outcomes 2—statistical significance and clinical meaningfulness: linking evidence to practice. J Orthop Sports Phys Ther. 2019;49:559-560. https://doi.org/10.2519/ jospt.2019.0704
- 5. Kamper SJ. Reliability and validity: linking evidence to practice. J Orthop Sports Phys Ther. 2019;49:286-287. https://doi.org/10.2519/ jospt.2019.0702
- Stratford PW, Binkley JM, Riddle DL, Guyatt GH. Sensitivity to change of the Roland-Morris Back Pain Questionnaire: part 1. Phys Ther. 1998;78:1186-1196. https://doi.org/10.1093/ptj/78.11.1186

"A difference is a difference only if it makes a difference." 2

DOWNLOAD PowerPoint Slides of *JOSPT* Figures

JOSPT offers PowerPoint slides of figures to accompany all full-text articles with figures on JOSPT's website (www.jospt.org). These slides are generated automatically by the site, and can be downloaded and saved. They include the article title, authors, and full citation. JOSPT offers full-text format for all articles published from January 2010 to date.

MUSCULOSKELETAL IMAGING



FIGURE 2. (A) Long-axis, axial, T2-weighted right-foot magnetic resonance image demonstrating cortical irregularity (arrow). (B) Sagittal, T1-weighted right-foot magnetic resonance image demonstrating signal hypointensity (arrow). (C) Sagittal, short-tau inversion recovery, weighted right-foot magnetic resonance image demonstrating signal hyperintensity (arrow) of the medial cuneiform without involvement of the plantar metatarsal ligaments, consistent with an isolated medial cuneiform impaction fracture.

Radiographically Occult Medial Cuneiform Impaction Fracture

LANCE M. MABRY, PT, DPT, Department of Physical Therapy, High Point University, High Point, NC. TAYLOR N. PATTI, SPT, Department of Physical Therapy, High Point University, High Point, NC. CHRIS M. BLEAKLEY, PT, PhD, Department of Physical Therapy, High Point University, High Point, NC.

25-YEAR-OLD WOMAN REPORTED TO the emergency department with right medial midfoot pain after kicking a wall, inducing a first-ray axial/plantar flexion compressive force. The patient was unable to weight bear immediately after the injury. Erythema and edema were present at the medial midfoot. Radiographs were noncontributory (FIGURE 1, available at www.jospt.org). The patient was diagnosed with a metatarsal contusion and was instructed to use ice and ibuprofen and to weight bear as tolerated on crutches.

The patient returned to full weight bearing 3 days later; however, persistent pain 3.5 weeks post injury led her to seek a direct-access physical therapy evaluation. Her pain was exacerbated with the first steps when getting out of bed and by walking barefoot. The examination revealed mild ecchymosis at the medial and plantar midfoot. During gait, the patient bore weight along the lateral foot to avoid pronation in stance and experienced 3/10 to 4/10 pain. The medial cuneiform was tender to palpation. Due to concern for a medial cuneiform fracture or a medial midfoot sprain, the physical therapist requested magnetic resonance imaging, which confirmed a medial cuneiform fracture (FIGURE 2; FIGURE 3, available at www. jospt.org).

The patient wore a cam boot for 2 weeks; transitioned to a flat, hard-soled shoe at 5 weeks post injury; and footwear restrictions were removed 6 weeks post injury. The patient returned to running and lunges with only mild discomfort 12 weeks post injury.

Isolated medial cuneiform fractures are commonly missed at baseline evaluation and are typically occult in initial radiographs.² Definitive diagnosis usually occurs after continued symptoms prompt advanced diagnostic imaging. Conservative management is commonly sufficient to restore prior function.¹ ● *J Orthop Sports Phys Ther* 2019;49(9):675. doi:10.2519/jospt.2019.8778

References

^{1.} Babu NS, Gambardella GV, Bowlby MA. Isolated fracture of the medial cuneiform: a case report. J Am Podiatr Med Assoc. 2017;107:436-439. https://doi.org/10.7547/16-013

^{2.} Eraslan A, Ozyurek S, Erol B, Ercan E. Isolated medial cuneiform fracture: a commonly missed fracture. BMJ Case Rep. 2013;2013:bcr2013010093. https://doi.org/10.1136/bcr-2013-010093

KELSEY J. PICHA, PhD, ATC¹ • MORGAN LESTER, DPT, SCS² • NICHOLAS R. HEEBNER, PhD, ATC²

John P. Abt, PhD, ATC² • Ellen L. Usher, PhD³ • Gilson Capilouto, PhD, CCC-SLP² • Tim L. Uhl, Pt, PhD, ACT²

The Self-Efficacy for Home Exercise Programs Scale: Development and Psychometric Properties

dherence to medical recommendations is essential to successful patient outcomes in rehabilitation. Home exercise programs (HEPs) act as a crucial adjunct to in-clinic rehabilitation, as they defer the cost of supervised physical therapy sessions while still providing a high level of care. Hayes et al²⁵ found that patients who had rotator cuff repair demonstrated comparable outcomes

whether they were allocated to individualized physical therapy or performed an unsupervised HEP. Despite the benefits of rehabilitative exercise, adherence is low. In the clinic, patient adherence is ap-

proximately 50%,³² and rates of HEP adherence are even lower.^{6,12} With the rising cost of health care, prescription of HEPs may lower the financial burden associated with injury by reducing the number

- BACKGROUND: The Self-Efficacy for Home Exercise Programs Scale (SEHEPS) was developed to help clinicians evaluate patients' self-efficacy for performing prescribed home exercise programs. Prior to clinical adoption, the scale's psychometric properties need to be examined.
- **OBJECTIVE:** To determine the psychometric properties of the SEHEPS.
- **METHODS:** Eighty-one patients (32 men, 49 women; mean \pm SD age, 42 \pm 17 years) with varying musculoskeletal conditions participated in this cohort study. Patients were given a home exercise program at the initial physical therapy visit and completed the SEHEPS and a modified Self-Efficacy for Exercise (SEE) scale. The SEHEPS is a 12-item patient-reported questionnaire designed to assess self-efficacy for prescribed home exercise. Patients rated their confidence on a 7-point scale that ranged from 0 (not confident) to 6 (very confident). Total scores ranged from 0 (low self-efficacy) to 72 (high self-efficacy). We assessed the internal consistency of the SEHEPS using Cronbach's alpha and its test-retest reliability using
- an intraclass correlation coefficient. Convergent validity between the SEHEPS and SEE scale was evaluated with a Spearman correlation.
- **RESULTS:** High internal consistency (α = .96) and good test-retest reliability (intraclass correlation coefficient = 0.88; SEM, 4; minimal detectable change at the 95% confidence level, 12) were demonstrated. The SEHEPS was strongly correlated with the SEE scale (ρ = 0.83, P<.01), indicating strong convergent validity.
- **CONCLUSION:** The SEHEPS demonstrates excellent internal consistency and convergent validity with the SEE scale. Overall, the SEHEPS is a clinically useful tool to evaluate a patient's self-efficacy in home-based musculoskeletal exercise programs. This scale can be used prior to prescribing a home exercise program for patients with musculoskeletal conditions.
- LEVEL OF EVIDENCE: Therapy, level 4.
 J Orthop Sports Phys Ther 2019;49(9):647-655.
 Epub 10 Jul 2019. doi:10.2519/jospt.2019.8779
- KEY WORDS: orthopaedics, rehabilitation, social cognitive theory, therapeutics

of clinic visits. However, nonadherence to prescribed HEPs may diminish the benefits of physical therapy.⁴⁶

Low self-efficacy is one of several barriers to rehabilitation exercise adherence and an important predictor of patient behavior.3,4,35 Self-efficacy refers to the beliefs individuals hold about their capability of successfully performing particular tasks. Those with higher levels of self-efficacy in performing exercise have been found to be 50% more likely to engage in exercise prescription. 43 Numerous studies have shown that self-efficacy is a robust predictor of exercise behavior and effort.8 Self-efficacy is not a trait characteristic; rather, individuals revise their perceived efficacy when facing different situations or tasks. Environmental circumstances can raise or lower individuals' self-efficacy. For example, behavioral intervention programs that target selfefficacy for exercise have revealed higher adherence rates (13%-30%) compared to

Though low self-efficacy is a known psychological barrier to rehabilitation exercise adherence, self-efficacy is not always assessed or addressed within the standard clinical practice for musculoskeletal rehabilitation. Patients with low self-efficacy may present with characteristics such as fear of failure, fear of risks or uncertainty, and low aspirations.³ On

¹Research Support, Department of Interdisciplinary Health Sciences, A.T. Still University, Mesa, A.Z. ²Department of Rehabilitation Sciences, The University of Kentucky, Lexington, KY. ³Department of Educational, School, and Counseling Psychology, The University of Kentucky, Lexington, KY. The University of Kentucky Institutional Review Board approved this study (protocol 17-0413-P3K). The authors certify that they have no affiliation with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the article. Address correspondence to Dr Kelsey Picha, 5850 East Still Circle, Mesa, AZ 85206. E-mail: kpicha@atsu.edu © Copyright ©2019 Journal of Orthopaedic & Sports Physical Therapy®

the other hand, patients with high self-efficacy often demonstrate self-confidence and can quickly recover after failing or having a setback with a task.³ The clinician's ability to recognize patients with low self-efficacy is important, as self-efficacy contributes to patient adherence to HEPs.

A variety of patient self-efficacy scales have been developed, and researchers have offered evidence of their reliability and validity for certain contexts. For instance, self-efficacy scales have been useful in identifying patients with low self-efficacy in cardiac rehabilitation⁵⁰ and in arthritic populations.³⁶ However, few, if any, scales have specifically assessed self-efficacy for HEPs among patients with musculoskeletal disorders. A proximate measure, the Self-Efficacy for Exercise (SEE) scale, has been previously correlated with in-clinic exercise (r = 0.34, P = .03), but not for home exercise (r = 0.14), indicating that this measure may not be the best choice to assess self-efficacy for HEPs.

Self-efficacy is situation and task specific, meaning that a general all-purpose measure may not give specific-enough information to the clinician.2 Using a proximate measure limits the value of the information collected, as the relevance to HEPs is not assessed in available measures.2 In addition, Bandura2 suggested that self-efficacy scales should be designed to specifically address activity domains and evaluate the multiple ways self-efficacy functions within a domain. To date, no scale has specifically addressed self-efficacy for HEPs. Developing an evaluation tool that clinicians could use to screen patients based on their self-efficacy in adhering to HEPs is necessary to further individualize patient care and overcome this barrier.

To date, no tool exists to evaluate self-efficacy in patients who are prescribed an HEP. The first aim of this study was to develop and evaluate a tool for assessing self-efficacy in adhering to an HEP, the Self-Efficacy for Home Exercise Programs Scale (SEHEPS). The researchers hypothesized that the SEHEPS would

demonstrate (1) good-to-excellent internal consistency (*α*≥.80), (2) acceptable test-retest reliability (intraclass correlation coefficient [ICC]>0.70), and (3) a significant positive relationship with 2 related measures, the SEE scale and the Pain Self-Efficacy Questionnaire (PSEQ). A secondary aim of this study was to determine a cutoff score that could identify nonadherent patients. The researchers hypothesized that self-efficacy for HEPs would positively correlate with reported adherence rates.

METHODS

Scale Development

■HE SEHEPS WAS MODIFIED FROM the SEE scale.⁵¹ As self-efficacy beliefs are linked to specific realms of functioning,2 a scale to assess self-efficacy for HEPs in musculoskeletal patients is essential. Item generation began by modifying the SEE scale from asking patients, "How confident are you right now that you could exercise 3 times per week for 20 minutes if . . . ?" to "How confident are you that you could perform the prescribed exercises correctly . . . ?" in relation to their prescribed HEP. To eliminate hypothetical thinking and acknowledge the presence of potential barriers, the word if was changed to when. The 9 items in the SEE scale were revised specifically to address questions related to HEPs, and 3 questions were added. These new questions were (1) "How confident are you that you could perform the prescribed exercises correctly as often as prescribed by your clinician?" (2) "How confident are you that you could perform exercises correctly when you are given written exercise instruction?" and (3) "How confident are you that you could perform exercises correctly when you do not have supervision or clinician feedback?"

Focus groups consisting of athletic trainers, physical therapists, and a self-efficacy expert reviewed the scale to provide evidence of face and content validity. The decision was made to modify the response scale from 11 points (0-100,

increasing in 10-point increments) to 7 points (0-6), which reduced the levels of discrimination in the scale as well as the cognitive burden on respondents. 40,49 The descriptors of "not confident," "somewhat confident," and "very confident" were also included. Scale anchors ranged from 0 (not confident) to 6 (very confident).

Previous literature has indicated that a similar response-scale format provides comparable results to a 0-to-100 scale. 44,49 Other self-efficacy scales have also used this rating system. 42 Upon scale finalization, a pilot test of the SEHEPS was conducted on a convenience sample of 10 patients in a physical therapy clinic. Pilot test results confirmed that patients understood scale items and could complete them in a reasonable time.

Survey Measures

The SEHEPS (APPENDIX, available at www.jospt.org) was designed to evaluate a patient's self-efficacy toward his or her prescribed HEP. This scale is a guide for clinicians to individualize patient care when HEPs are utilized. The 12-item questionnaire takes approximately 2 minutes to complete. A patient's self-efficacy score was calculated as the raw sum score of the 12 self-efficacy items (possible range, 0-72). Patients completed the SEHEPS at 2 time points: the initial visit and 24 to 48 hours following the initial visit.

The SEE Scale was designed to examine the barriers to exercise self-efficacy in adults. This 9-item scale asks individuals to rate their confidence that they can exercise for 20 minutes, 3 times a week, under certain conditions. Typically, responses are rated on a 0-to-10-point Likert scale, but the response options were reduced to a 7-point Likert scale for this study to keep formatting consistent across scales and thereby eliminate patient confusion.⁵⁷ The SEE scale was created to assess sedentary adults' perceived capability to take part in various exercises (ie, biking, rowing, and walking) in the presence of barriers.⁵¹ The 10-point SEE scale has been identified as reliable and

valid within the older adult population.⁵¹ Stronger self-efficacy expectations detected on this scale have been associated with better physical and mental health status.⁵¹ This scale was administered only at the initial visit to examine convergent validity between the SEHEPS and SEE scale.

The PSEQ is applicable to many patients suffering from persistent pain.42 This scale was developed to examine individuals' confidence in their ability to complete activities while experiencing pain. The PSEQ has high internal consistency ($\alpha = .92$) and test-retest reliability (ICC = 0.73).42 Pain-related disability and coping strategies are correlated with the PSEQ.42 Researchers have also examined the effects of a cognitive behavioral intervention on chronic pain with the PSEQ.55 This scale was administered only at the initial visit to examine convergent validity between the SEHEPS and the PSEQ.

The Global Rating of Change question is a 1-item questionnaire that determines meaningful change in a patient's condition on a Likert scale ranging from -5 (much worse) to +5 (much better). 29,30,58 This measure was used to determine whether patients perceived their health status to have changed at 24 to 48 hours post treatment, before a change in health status could hinder their ability to complete their prescribed HEP. Patients who scored between -2 and +2 were considered to be in the same condition that they were in the previous day and were asked to complete the SEHEPS questionnaire again to evaluate its test-retest reliability.39 Patients outside this range were not analyzed. The global rating of change question has been determined to be reliable and valid.29,30

Participants

This study included 81 patients who were being treated for a musculoskeletal condition. Participants were between 18 and 70 years of age, prescribed an HEP, and expected to receive treatment for at least 2 weeks. Patients were excluded if they did not intend to return for follow-up visits or were unable to read English.

Study Design and Procedures

This study examined the psychometric properties of the SEHEPS in a clinical cohort. Patients were recruited at their initial physical therapy visit at 1 of 2 outpatient orthopaedic clinics, by 1 of 3 trained raters. After participants were informed about the study and provided verbal and written consent (per protocol 17-0413-P3K approved by The University of Kentucky Institutional Review Board), they were administered the SEHEPS, SEE scale, and PSEQ. Following the prescription of an HEP, the 3 questionnaires took approximately 10 minutes to complete. Patients received an exercise log in which to record their prescribed HEP over 2 to 4 weeks by checking a box (yes or no) to indicate whether they had completed the prescribed exercises. The adherence percentage was calculated as (days HEP was completed/days HEP was prescribed) × 100. The period of 2 to 4 weeks was based on the 30-day window for physical therapy progress reports, leaving time to follow up when a patient was discharged prior to the progress report. Participants were given instructions on how to fill out the exercise log and asked to return the log at the end of the study.

The following day, patients received an e-mail requesting that they complete the

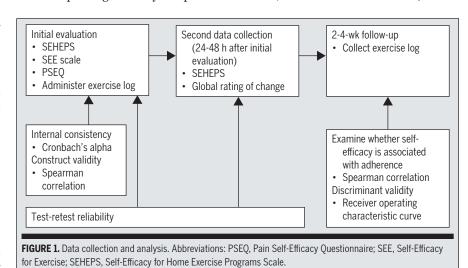
global rating of change question and the SEHEPS within 24 to 48 hours of their initial visit. The survey was completed via Research Electronic Data Capture (REDCap; Vanderbilt University, Nashville, TN), a secure, web-based application designed to support data capture for research studies.²⁴

The last follow-up occurred between 2 and 4 weeks after re-evaluation, when patients returned their exercise logs to complete the study. **FIGURE 1** presents the timing of data collection and analysis.

Statistical Analysis

The psychometric properties of the SEH-EPS were examined from several perspectives. Cronbach's alpha was used to evaluate internal consistency of the item responses. Test-retest reliability of the SEHEPS was determined using ICC model 2,1⁵⁴ between the first and second assessment. Evidence for convergent validity was obtained by examining the correlation between scale scores obtained at the initial visit. Relationships between the 3 initial self-efficacy scores were examined with a Spearman rho, with correlations categorized as weak or low (below 0.50), moderate (0.50-0.70), or strong (above 0.70).²⁶

The second aim of the study, to determine a cutoff score for nonadherence, was achieved with a receiver operating characteristic curve to differentiate patients at a 70% HEP adherence rate, which



ries had to be combined, as indicated in

TABLE 1. For example, because some cat-

egories of socioeconomic status included

represents the high end of patient adherence.7,32,53 The receiver operating characteristic curve plotted sensitivity by 1 minus specificity for SEHEPS scores. The balance point, maximizing both sensitivity and specificity, determined the cut score for likely nonadherence, which could only be calculated from returned exercise logs. The P value for the area under the curve was set at .05. All statistical analysis was completed using SPSS statistical software (Version 24.0; IBM Corporation, Armonk, NY).

only 1 patient, the mid-tier, at-risk, and distressed groups were combined into 1 more-distressed group for analysis.

No differences in age, sex, race, socioeconomic status, or condition were detected between those who returned their exercise log and those who did not

(TABLE 1). Patient diagnoses are displayed in TABLE 2. Statistical analysis was then performed only on the 32 individuals who returned their exercise log to evaluate the relationship between adherence to home exercise and self-efficacy at the initial visit. The Spearman rho correlation coefficient between the SEHEPS at the initial visit and program adherence was significant (n = 32, ρ = 0.38, P = .03).

RESULTS

Patient Characteristics and Descriptive Statistics

■ IGHTY-ONE PATIENTS WITH MUSCUloskeletal conditions volunteered to participate. Participants were contacted several times via e-mail, text, or phone call to encourage them to return their exercise logs, resulting in a response rate of 39.5% (n = 32). Patients were asked to report whether they had completed the HEP prescribed by their physical therapist and no other details regarding exercise performance. Of those who returned their logs, the average adherence rate was 76%. TABLE 1 includes patient characteristics and compares the demographics between patients who returned their exercise logs and those who did not. Independent t tests were used to evaluate differences between continuous variables (age and previous rehabilitation).

Chi-square tests assessed dichotomous and categorical variables (sex, race, insurance, socioeconomic status, and previous rehabilitation). Socioeconomic status was determined by zip code, using the 2017 Distressed Communities Index,15 with scores ranging from 1 to 100, with a higher score indicating a more distressed community. Typically, the Distressed Communities Index scores are categorized into 5 groups: prosperous (below 20), comfortable (20-40), mid-tier (40-60), at risk (60-80), and distressed (over 80). Due to the small sample size of this cohort, some of the demographic catego-

TABLE 1 Patient Characteristics* Log Returned No Log Returned Characteristic All (n = 81)(n = 32)(n = 49)P Value 44.2 ± 17.4 42 ± 17 40.4 ± 17.5 .35 Age, y Sex, n .39 Male 32 11 21 49 21 28 Female Race, n .62 27 39 Caucasian 12 8 Other 4 3 2 Λ Not reported Insurance, n .60 Private 65 25 40 Public 12 6 6 Not reported 4 3 Socioeconomic status, n .16

13

8

11

21

22

6

11

20

16

21

28

26

14

.45

.23

24

28

25

32

49

48

20

13 4 9 Not reported 50.8 ± 13.6 52.6 ± 11.6 49.7 ± 14.7 SEHEPS initial score .34 20-72 SEE scale score 37.3 ± 10.8 38.9 ± 9.5 35.9 ± 11.3 .21 Range 10-54 PSEQ score 42.1 ± 13.7 43.9 ± 13.1 40.6 ± 13.9 .29 8-70

Abbreviations: PSEQ, Pain Self-Efficacy Questionnaire; SEE, Self-Efficacy for Exercise; SEHEPS, Self-Efficacy for Home Exercise Programs Scale.

- *Values are mean \pm SD unless otherwise indicated.
- *Based on the 2017 Distressed Communities Index.15
- $^{ ext{+}}$ "Previous rehabilitation" refers to patients who attended rehabilitation in the past for the same or a $different\ musculos keletal\ condition.$

Prosperous

Comfortable

Less than comfortable

(from mid-tier to

distressed)

Postsurgical patient, n

Previous rehabilitation, n[‡]

Yes

Nο

Yes

No

Reliability

The internal consistency estimate for the items in the SEHEPS was deemed to be high (α = .96) among all 81 participants at the initial visit. Test-retest reliability was calculated using the SEHEPS score at the initial visit and at the 24- to 48hour follow-up. The test-retest reliability analysis, which included 20 of the 81 participants, found the SEHEPS to be reliable between days (ICC = 0.88; SEM, 4; minimal detectable change at the 95% confidence level [MDC₉₅], 12).

Validity

Convergent validity was strong between the SEHEPS and SEE scale ($\rho = 0.83$, P<.01) (FIGURE 2) and low between the SEHEPS and PSEQ (ρ = 0.31, P<.01) (FIG-**URE 3**). The correlation for the assessment of convergent validity was significant, but slightly weaker, between the SEE scale and PSEQ ($\rho = 0.28, P < .01$) (**FIGURE 4**). In a secondary analysis, independent t tests assessed initial SEHEPS scores between patients who had surgery and those who did not. There were no differences in SEHEPS scores between nonsurgical (50.8 \pm 12.2) and surgical (50.7 \pm 15.7) groups (P>.05), supporting the external validity of the instrument in both patient populations.

Cutoff Scores

The SEHEPS cutoff score to identify patients who were not adherent to their prescribed HEP at the 70% level was determined by receiver operating characteristic curve analysis (FIGURE 5). The area under the curve was 0.78, with a standard error of 0.08, which was significant (P = .008). The

cutoff score was 59 points, with a sensitivity of 92% (95% confidence interval [CI]: 66%, 99%) and specificity of 55% (95% CI: 40%, 60%). The positive likelihood ratio of 2.0 (95% CI: 1.1, 2.5) indicates that those who scored below 59 points on the SEH-EPS were twice as likely to be nonadherent than adherent to their HEP.

Missing Data

Seven patients chose the "not applicable" option on the initial SEHEPS at least once, 2 of whom returned their exercise logs. To handle missing data, the authors ran analyses on the relationship between self-efficacy and HEP adherence with (n = 30) and without (n = 32) missing data. Results were not altered (if included, r =0.38 and P = .03; if excluded, r = 0.39and P = .04). Therefore, a raw score could be used when only 1 to 2 responses were missing, with the understanding that the total score should be reduced by 6 points per unanswered question. If more than 2 items were left unanswered, scores should be used with caution.

DISCUSSION

ATIENT ADHERENCE TO HEPS HAS been reported to be as low as 13%. 16,53 The assessment of patient barriers, such as low self-efficacy, is essential for improving and individualizing care. This study provides a newly developed scale with strong psychometric properties to aid in assessing patients' self-efficacy for HEPs. Results of this study demonstrate that the SEHEPS is a reliable and valid tool to assess self-efficacy in both musculoskeletal surgical and nonsurgical patient populations participating in HEPs. Clinically, assessment of self-efficacy using this scale may aid in identifying which patients may not be adherent to their HEPs.

Items on the SEHEPS have excellent internal consistency. This scale should be used with caution, as acceptable Cronbach's alpha values vary between research and clinical use.10 A Cronbach's alpha of .96 suggests that this scale is suitable for both research and clinical application,

TABLE 2 PATIENT DIAGNOS	SES
Diagnosis	n
Surgical	
ACL reconstruction	11
Meniscus repair	5
Shoulder repair	5
Loose-body removal from knee	4
Total lower extremity arthroplasty	4
Medial patellofemoral ligament reconstruction	1
Metacarpal fracture with percutaneous pinning	1
Total	31
Nonsurgical	
Shoulder pain	14
Back pain	7
Ankle sprain	5
Knee pain	6
Hip pain	5
Ankle/foot fracture	3
Neck pain	3
Achilles tendinopathy	1
Patellar dislocation	1
Compartment syndrome	1
Clavicular fracture	1
Ankle osteoarthritis	1
Lateral epicondylitis	1
Wrist pain	1
Total	50
Abbreviation: ACL, anterior cruciate ligament.	

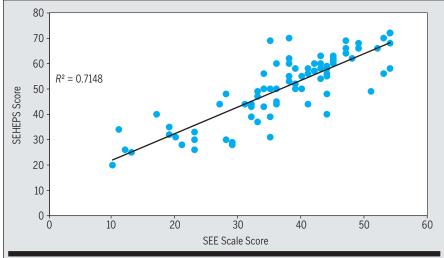


FIGURE 2. Correlation between initial SEHEPS score and SEE scale score. Abbreviations: SEE, Self-Efficacy for Exercise; SEHEPS, Self-Efficacy for Home Exercise Programs Scale.

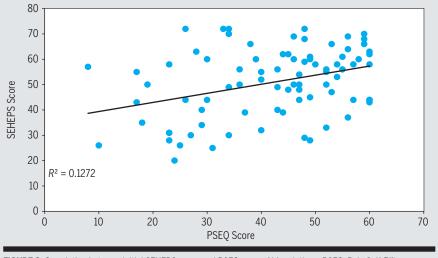


FIGURE 3. Correlation between initial SEHEPS score and PSEQ score. Abbreviations: PSEQ, Pain Self-Efficacy Questionnaire; SEHEPS, Self-Efficacy for Home Exercise Programs Scale.

though it is slightly higher than that obtained with related self-efficacy scales, which may indicate that the items in the scale do not provide enough variability or that reduction of items may be possible. Future studies may reduce the items in this scale using a factor-analysis technique. A scale with fewer items would save both the patient and clinician time, yet provide valuable information for further individualization of care. Other self-efficacy measures, such as the SEE scale and the PSEQ, also have excellent internal consistency (.92),^{42,51} but this is the first scale to

specifically assess self-efficacy for HEPs.

Evaluation of test-retest reliability of the SEHEPS separates this scale from other self-efficacy assessment tools such as the SEE scale, which do not report this psychometric property. Only 4 self-efficacy scales used within the musculoskeletal literature provided a value for test-retest reliability. ^{36,38,42,56} The test-retest reliability of the SEHEPS is considered to be good ⁴⁸ and is higher than that of the PSEQ (ICC = 0.73) and similar to that of the Arthritis Self-Efficacy Scale (ICC = 0.85-0.90). ³⁶ This finding indicates that

the SEHEPS is a stable assessment of self-efficacy for HEPs.

It is important that clinicians have reliable measures to assess patient selfefficacy for HEPs, as they may help to individualize care. The SEM of 4 and MDC₉₅ of 12 do not exceed 10% error of the total score of the instrument, which is consistent with other patient-reported scales to assess musculoskeletal injury. 18,19,22,41 Establishing these values is important to researchers who may use this scale to assess the effectiveness of a self-efficacy intervention to improve functional outcomes or exercise adherence. These findings suggest that, when utilizing this tool to assess a patient's selfefficacy for an HEP, a 7-point change in total score indicates real change.

This study establishes evidence for the face, content, and convergent validity of the SEHEPS. A strong, positive correlation was detected between the SEHEPS and the SEE scale, which is consistent with our hypothesis. A weaker correlation was found between the SEHEPS and PSEQ. This may be because PSEQ questions relate to pain during other activities besides exercise alone, whereas the SEHEPS is specific to HEPs. A secondary analysis found that the SEE scale had a similar relationship to the PSEQ, which may also be a result of the different tasks in question. These results provide support for the SEHEPS as measuring the construct of self-efficacy relating to exercise rather than to pain.

This scale was created with the intent of specifically measuring self-efficacy as it pertains to HEPs to help clinicians better decipher who may be nonadherent to prescribed programs. At the initial visit, patients who scored less than 59 points (the cutoff score) on the SEHEPS were 2 times less likely to adhere to their HEPs. The relationship between reported HEP adherence and SEHEPS score at the initial visit is significant but low (ρ = 0.38) (**FIGURE 6**), similar to that found in previous studies of self-efficacy for different tasks or situations. Although a small sample might have contributed to this

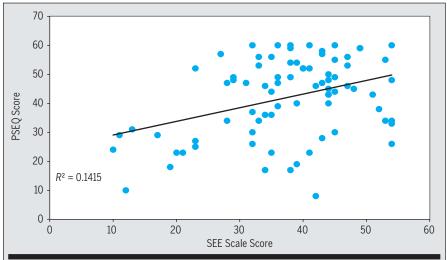


FIGURE 4. Correlation between SEE scale score and PSEQ score. Abbreviations: PSEQ, Pain Self-Efficacy Questionnaire; SEE, Self-Efficacy for Exercise.

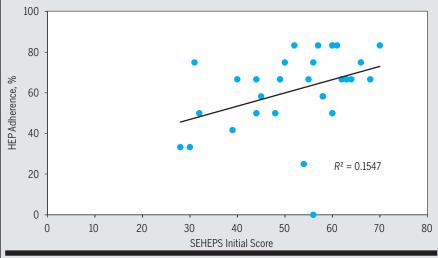


FIGURE 6. Correlation between initial SEHEPS score and adherence to the HEP. Abbreviations: HEP, home exercise program; SEHEPS, Self-Efficacy for Home Exercise Programs Scale.

correlation, it is in line with a similar finding from Mannion et al, 37 who reported a slightly weaker correlation (r = 0.36) between adherence to home exercise and self-efficacy (assessed via the Exercise Self-Efficacy Scale). The relatively low correlation may be due to the specificity of the task (prescribed HEPs) inquired about in the new scale.

Other studies of the relationship between exercise self-efficacy and adherence have found positive yet weak to moderate relationships (r=0.30-0.39). Many of these studies used a Pearson

correlation coefficient to examine these relationships, whereas this study used a Spearman correlation coefficient, due to nonnormal data distribution. The use of the Spearman correlation coefficient may have produced slightly different values from those obtained via the Pearson correlation coefficient.

Lower self-efficacy may result in decreased adherence to both clinic-based exercise and attendance at physical therapy treatments. These results illustrate that self-efficacy is a construct that may impact maintenance and adherence

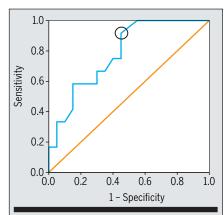


FIGURE 5. Receiver operating characteristic curve for the Self-Efficacy for Home Exercise Programs Scale. The point closest to the top left corner (circle) is the cutoff score that demonstrates the best balance between sensitivity and specificity of those patients likely to be nonadherent to their home exercise program.

to rehabilitative exercise.³⁴ The current study provides a more task-specific scale for assessing self-efficacy for HEPs.

When making clinical decisions regarding patient adherence to HEPs, the SEHEPS may help clinicians discriminate between those who may and may not be at least 70% adherent. The balance point of sensitivity and specificity on the SEHEPS identified a cutoff score of 59, classifying 22 out of 32 patients correctly. These results may help clinicians pursue early interventions to improve patient self-efficacy or modify HEPs to ensure exercise adherence. For the average patient who scores 50 points on the SEHEPS, an improvement of as little as 7 points would come closer to the 59-point cutoff score, making the patient less likely to be nonadherent. Previous studies have found that goal setting, providing systematic feedback and additional social support through text messages or e-mail, and education to enhance behavioral change or self-management have increased patient self-efficacy and, in turn, adherence. 17,28,31,33,45 After the administration of the SEHEPS at the initial visit, any of these interventions may be easily incorporated into the standard of care.

Study Limitations

Without the patients' exercise logs, we were unable to determine whether the

results were skewed between self-efficacy at the initial visit and adherence to the prescribed HEP. Despite numerous attempts to obtain these logs, patients claimed to have lost their logs or no longer wished to participate. Another construct to consider in social cognitive theory to account for low return of exercise logs is selfregulation. Bandura⁵ has suggested that self-regulation is a key factor in one's life outcomes and that "people are not eager to shoulder the burdens of responsibility."5 Whether completing an HEP or returning an exercise log, some individuals may not self-regulate or manage such tasks as they should to improve their condition. Low response rates are a common problem in human research,23 and this study was no exception. However, the data collected at the initial visit were not affected by this, as internal consistency and validity were not reliant on response rate.

The authors did not control for other possible sources of variation, such as care provided by clinicians, progression of therapy, or patient diagnosis. Future studies should account for these variables, as some patients may respond better to self-efficacy interventions. The purpose of the present study was to examine the use of this instrument in standard physical therapy care in a musculoskeletal setting for prescribed home exercise only. Consequently, other essential aspects of a home program, such as activity modification and ergonomic changes, are not addressed. This is a limitation that should be considered in future studies.

This scale should be refined with further research through factor analysis, item reduction, and confirmatory factor analysis. Use of this scale when implementing a self-efficacy intervention to stratify patients into groups based on level of self-efficacy should also be considered.

CONCLUSION

HIS STUDY DEVELOPED AND TESTED a new tool to help clinicians assess patients' self-efficacy when completing HEPs. The SEHEPS had

strong evidence of internal consistency, test-retest reliability, and convergent validity, providing support for its use in a musculoskeletal patient population. The SEHEPS may be a clinically useful tool for evaluating patient self-efficacy for HEPs, as a score below 59 points indicated twice the risk of nonadherence. This scale provides a first step toward facilitating a patient's adherence to exercise prescription, which may improve rehabilitation outcomes.

•

EXEV POINTS

FINDINGS: The Self-Efficacy for Home Exercise Programs Scale (SEHEPS) was developed to assist clinicians in the assessment of patient self-efficacy for home exercise programs (HEPs). The SEHEPS is a reliable and valid tool that can be implemented in clinical practice. IMPLICATIONS: Patients who scored below 59 points on the SEHEPS were 2 times more likely to be nonadherent to their prescribed HEP. Clinicians may consider using the SEHEPS to intervene early in the plan of care.

CAUTION: This study had a small sample of exercise logs returned, making it difficult to determine whether the results were skewed between self-efficacy at the initial visit and adherence to HEPs.

REFERENCES

- Annesi J. Effects of a cognitive behavioral treatment package on exercise attendance and drop out in fitness centers. Eur J Sport Sci. 2003;3:1-16. https://doi.org/10.1080/17461390300073206
- Bandura A. Guide for creating self-efficacy scales. In: Pajares F, Urdan T, eds. Self-Efficacy Beliefs of Adolescents. Greenwich, CT: Information Age; 2006:307-338.
- Bandura A. Self-efficacy. In: Ramachandran VS, ed. *Encyclopedia of Human Behavior Volume* 4. San Diego, CA: Academic Press; 1994:71-81.
- **4.** Bandura A. Self-Efficacy: The Exercise of Control. New York, NY: W.H. Freeman; 1997.
- Bandura A. Social cognitive theory: an agentic perspective. *Annu Rev Psychol*. 2001;52:1-26. https://doi.org/10.1146/annurev.psych.52.1.1
- **6.** Bassett SF. The assessment of patient adherence to physiotherapy rehabilitation. *NZ J Physiother*. 2003;31:60-66.
- 7. Beinart NA, Goodchild CE, Weinman JA, Ayis S,

- Godfrey EL. Individual and intervention-related factors associated with adherence to home exercise in chronic low back pain: a systematic review. *Spine J.* 2013;13:1940-1950. https://doi.org/10.1016/j.spinee.2013.08.027
- Berarducci A, Lengacher CA. Self-efficacy: an essential component of advanced-practice nursing. Nursingconnections. 1998;11:55-67.
- Bishara AJ, Hittner JB. Testing the significance of a correlation with nonnormal data: comparison of Pearson, Spearman, transformation, and resampling approaches. *Psychol Methods*. 2012;17:399-417. https://doi.org/10.1037/a0028087
- Bland JM, Altman DG. Cronbach's alpha. BMJ. 1997;314:572. https://doi.org/10.1136/ bmj.314.7080.572
- Brewer BW, Cornelius AE, Van Raalte JL, et al. Protection motivation theory and adherence to sport injury rehabilitation revisited. Sport Psychol. 2003;17:95-103. https://doi.org/10.1123/tsp.17.1.95
- Chan D, Can F. Patients' adherence/compliance to physical therapy home exercises. Fizyoter Rehabil. 2010;21:132-139.
- Chen CY, Neufeld PS, Feely CA, Skinner CS. Factors influencing compliance with home exercise programs among patients with upper-extremity impairment. Am J Occup Ther. 1999;53:171-180. https://doi.org/10.5014/ajot.53.2.171
- 14. Cheung C, Wyman JF, Savik K. Adherence to a yoga program in older women with knee osteoarthritis. J Aging Phys Act. 2016;24:181-188. https://doi. org/10.1123/japa.2015-0048
- Economic Innovation Group. The 2017 Distressed Communities Index. Washington, DC: Economic Innovation Group; 2017.
- Essery R, Geraghty AW, Kirby S, Yardley L.
 Predictors of adherence to home-based physical
 therapies: a systematic review. *Disabil Rehabil*.
 2017;39:519-534. https://doi.org/10.3109/0963828
 8.2016.1153160
- 17. Evans L, Hardy L. Injury rehabilitation: a goal-setting intervention study. Res Q Exerc Sport. 2002;73:310-319. https://doi.org/10.1080/0270136 7.2002.10609025
- Fairbank JC, Pynsent PB. The Oswestry Disability Index. Spine (Phila Pa 1976). 2000;25:2940-2952; discussion 2952.
- 19. 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;94:149-158. https://doi.org/10.1016/S0304-3959(01)00349-9
- 20. Florez-García M, García-Pérez F, Curbelo R, et al. Efficacy and safety of home-based exercises versus individualized supervised outpatient physical therapy programs after total knee arthroplasty: a systematic review and metaanalysis. Knee Surg Sports Traumatol Arthrosc. 2017;25:3340-3353. https://doi.org/10.1007/ s00167-016-4231-x
- Grindley EJ, Zizzi SJ, Nasypany AM. Use of protection motivation theory, affect, and barriers to understand and predict adherence to outpatient rehabilitation. *Phys Ther*. 2008;88:1529-1540.

- https://doi.org/10.2522/ptj.20070076
- 22. Gummesson C, Ward MM, Atroshi I. The shortened disabilities of the arm, shoulder and hand questionnaire (Quick DASH): validity and reliability based on responses within the full-length DASH. BMC Musculoskelet Disord. 2006;7:44. https://doi. org/10.1186/1471-2474-7-44
- 23. Hardage J, Peel C, Morris D, et al. Adherence to Exercise Scale for Older Patients (AESOP): a measure for predicting exercise adherence in older adults after discharge from home health physical therapy. J Geriatr Phys Ther. 2007;30:69-78.
- 24. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42:377-381. https://doi.org/10.1016/j. jbi.2008.08.010
- 25. Hayes K, Ginn KA, Walton JR, Szomor ZL, Murrell GA. A randomised clinical trial evaluating the efficacy of physiotherapy after rotator cuff repair. Aust J Physiother. 2004;50:77-83. https://doi. org/10.1016/S0004-9514(14)60099-4
- **26.** Hinkle DE, Wiersma W, Jurs SG. Applied Statistics for the Behavioral Sciences. 5th ed. Boston, MA: Houghton Mifflin; 2002.
- 27. Holden MA, Haywood KL, Potia TA, Gee M, McLean S. Recommendations for exercise adherence measures in musculoskeletal settings: a systematic review and consensus meeting (protocol). Syst Rev. 2014;3:10. https://doi.org/10.1186/2046-4053-3-10
- 28. Hughes SL, Seymour RB, Campbell R, Pollak N, Huber G, Sharma L. Impact of the fit and strong intervention on older adults with osteoarthritis. Gerontologist. 2004;44:217-228. https://doi. org/10.1093/geront/44.2.217
- 29. Kamper S. Global Rating of Change scales. Aust J Physiother. 2009;55:289. https://doi.org/10.1016/ S0004-9514(09)70015-7
- 30. Kamper SJ, Maher CG, Mackay G. Global rating of change scales: a review of strengths and weaknesses and considerations for design. J Man Manip Ther. 2009;17:163-170. https://doi. org/10.1179/jmt.2009.17.3.163
- 31. King SJ, Wessel J, Bhambhani Y, Sholter D, Maksymowych W. The effects of exercise and education, individually or combined, in women with fibromyalgia. J Rheumatol. 2002;29:2620-2627.
- 32. Kolt GS, McEvoy JF. Adherence to rehabilitation in patients with low back pain. Man Ther. 2003;8:110-116. https://doi.org/10.1016/ S1356-689X(02)00156-X
- 33. Levinger P, Hallam K, Fraser D, et al. A novel websupport intervention to promote recovery following Anterior Cruciate Ligament reconstruction: a pilot randomised controlled trial. Phys Ther Sport. 2017;27:29-37. https://doi.org/10.1016/ j.ptsp.2017.06.001
- 34. Levy AR, Polman RC, Clough PJ. Adherence to sport injury rehabilitation programs: an integrated psycho-social approach. Scand J Med Sci Sports. 2008;18:798-809. https://doi. org/10.1111/j.1600-0838.2007.00704.x

- 35. Lewis BA, Marcus BH, Pate RR, Dunn AL. Psychosocial mediators of physical activity behavior among adults and children. Am J Prev Med. 2002;23:26-35. https://doi.org/10.1016/ S0749-3797(02)00471-3
- **36.** Lorig K, Chastain RL, Ung E, Shoor S, Holman HR. Development and evaluation of a scale to measure perceived self-efficacy in people with arthritis. Arthritis Rheum. 1989;32:37-44. https://doi. org/10.1002/anr.1780320107
- 37. Mannion AF, Helbling D, Pulkovski N, Sprott H. Spinal segmental stabilisation exercises for chronic low back pain: programme adherence and its influence on clinical outcome. Eur Spine J. 2009;18:1881-1891. https://doi.org/10.1007/ s00586-009-1093-7
- 38. Marcus BH, Selby VC, Niaura RS, Rossi JS. Self-efficacy and the stages of exercise behavior change. Res Q Exerc Sport. 1992;63:60-66. https:// doi.org/10.1080/02701367.1992.10607557
- 39. Michener LA, McClure PW, Sennett BJ. American Shoulder and Elbow Surgeons Standardized Shoulder Assessment Form, patient self-report section: reliability, validity, and responsiveness. J Shoulder Elbow Surg. 2002;11:587-594. https://doi. org/10.1067/mse.2002.127096
- **40.** Miller GA. The magical number seven, plus or minus two: some limits on our capacity for processing information. Psychol Rev. 1956;63:81-97. https://doi.org/10.1037/h0043158
- 41. Mintken PE, Glynn P, Cleland JA. Psychometric properties of the Shortened Disabilities of the Arm, Shoulder, and Hand Questionnaire (QuickDASH) and Numeric Pain Rating Scale in patients with shoulder pain. J Shoulder Elbow Surg. 2009;18:920-926. https://doi.org/10.1016/j. jse.2008.12.015
- 42. Nicholas MK. The Pain Self-Efficacy Questionnaire: taking pain into account. Eur J Pain. 2007;11:153-163. https://doi.org/10.1016/j.ejpain.2005.12.008
- 43. Oliver K, Cronan T. Predictors of exercise behaviors among fibromyalgia patients. Prev Med. 2002;35:383-389. https://doi.org/10.1006/ pmed.2002.1084
- 44. Pajares F, Hartley J, Valiante G. Response format in writing self-efficacy assessment: greater discrimination increases prediction. Meas Eval Couns Dev. 2001;33:214-221.
- 45. Palmer S, Domaille M, Cramp F, et al. Transcutaneous electrical nerve stimulation as an adjunct to education and exercise for knee osteoarthritis: a randomized controlled trial. Arthritis Care Res (Hoboken). 2014;66:387-394. https://doi.org/10.1002/acr.22147
- 46. Picha KJ, Howell DM. A model to increase rehabilitation adherence to home exercise programmes in patients with varying levels of selfefficacy. Musculoskeletal Care. 2018:16:233-237. https://doi.org/10.1002/msc.1194
- 47. Pisters MF, Veenhof C, Schellevis FG, Twisk JW, Dekker J, De Bakker DH. Exercise adherence improving long-term patient outcome in patients with osteoarthritis of the hip and/or knee. Arthritis Care Res (Hoboken). 2010;62:1087-1094. https://

- doi.org/10.1002/acr.20182
- 48. Portney LG, Watkins MP. Foundations of Clinical Research: Applications to Practice. 3rd ed. Upper Saddle River, NJ: Pearson/Prentice Hall; 2008.
- 49. Preston CC, Colman AM. Optimal number of response categories in rating scales: reliability, validity, discriminating power, and respondent preferences. Acta Psychol (Amst). 2000;104:1-15. https://doi.org/10.1016/S0001-6918(99)00050-5
- 50. Rajati F, Sadeghi M, Feizi A, Sharifirad G, Hasandokht T, Mostafavi F. Self-efficacy strategies to improve exercise in patients with heart failure: a systematic review. ARYA Atheroscler. 2014;10:319-333.
- 51. Resnick B, Jenkins LS. Testing the reliability and validity of the Self-Efficacy for Exercise Scale. Nurs Res. 2000;49:154-159. https://doi. org/10.1097/00006199-200005000-00007
- 52. Seghers J., Van Hoecke AS, Schotte A, Opdenacker J, Boen F. The added value of a brief self-efficacy coaching on the effectiveness of a 12-week physical activity program. J Phys Act Health. 2014;11:18-29. https://doi.org/10.1123/jpah.2011-0445
- 53. Sluijs EM, Kok GJ, van der Zee J. Correlates of exercise compliance in physical therapy. Phys Ther. 1993;73:771-782; discussion 783-786. https://doi. org/10.1093/ptj/73.11.771
- **54.** Streiner DL, Norman GR. Health Measurement Scales. A Practical Guide to Their Development and Use. 2nd ed. Oxford, UK: Oxford University Press: 1995.
- 55. Taylor SJ, Carnes D, Homer K, et al. Novel threeday, community-based, nonpharmacological group intervention for chronic musculoskeletal pain (COPERS): a randomised clinical trial. PLoS Med. 2016;13:e1002040. https://doi.org/10.1371/journal. pmed.1002040
- **56.** Thomeé P, Währborg P, Börjesson M, Thomeé R, Eriksson BI, Karlsson J. A new instrument for measuring self-efficacy in patients with an anterior cruciate ligament injury. Scand J Med Sci Sports. 2006;16:181-187. https://doi. org/10.1111/i.1600-0838.2005.00472.x
- 57. Toland MD, Usher EL. Assessing mathematics self-efficacy: how many categories do we really need? J Early Adolesc. 2016;36:932-960. https:// doi.org/10.1177/0272431615588952
- 58. Walenkamp MM, de Muinck Keizer RJ, Goslings JC, Vos LM, Rosenwasser MP, Schep NW. The minimum clinically important difference of the Patient-rated Wrist Evaluation score for patients with distal radius fractures. Clin Orthop Relat Res. 2015;473:3235-3241. https://doi.org/10.1007/ s11999-015-4376-9



[RESEARCH REPORT]

APPENDIX

SELF-EFFICACY FOR HOME EXERCISE PROGRAMS SCALE

Please circle your level of confidence in completing your prescribed exercises at home.

How confident are you that you could perform the								
prescribed exercises correctly		Not Confident		Somewhat Confident			Very Confident	
as often as prescribed by your clinician?	NA	0	1	2	3	4	5	6
when you are bored by the program?	NA	0	1	2	3	4	5	6
when you feel pain when exercising?	NA	0	1	2	3	4	5	6
when you have to exercise alone?	NA	0	1	2	3	4	5	6
when you do not enjoy it?	NA	0	1	2	3	4	5	6
when you are given written exercise instruction?	NA	0	1	2	3	4	5	6
when you are too busy with other activities?	NA	0	1	2	3	4	5	6
when you are given video exercise instruction?	NA	0	1	2	3	4	5	6
when you feel tired?	NA	0	1	2	3	4	5	6
when you feel stressed?	NA	0	1	2	3	4	5	6
when you feel depressed?	NA	0	1	2	3	4	5	6
when you do not have supervision or clinician feedback?	NA	0	1	2	3	4	5	6

Abbreviation: NA, not applicable.

MARTA RÍOS-LEÓN, PT, MSc¹ • RICARDO ORTEGA-SANTIAGO, PT, PhD^{2,3} • PASCAL MADELEINE, PhD, DrScient⁴ CÉSAR FERNÁNDEZ-DE-LAS-PEÑAS, PT, MSc, PhD, DrScient^{2,3} • GUSTAVO PLAZA-MANZANO, PT, PhD^{5,6}

Topographical Pressure Pain Sensitivity Maps of the Feet Reveal Bilateral Pain Sensitivity in Patients With Unilateral Plantar Heel Pain

lantar heel pain, or plantar fasciitis, is one of the most common foot pain conditions treated by health care providers.

Individuals with plantar fasciitis report insidious sharp pain under the plantar surface of the heel, along the medial border of the plantar fascia to its insertion at the medial tuberosity of the calcaneus bone.

The pain increases in the morning with the first step after getting out of bed, after prolonged periods of inactivity, and at the

- BACKGROUND: Plantar heel pain is one of the most common foot pain conditions treated by health care providers.
- OBJECTIVES: To investigate differences in topographical pressure pain sensitivity maps of the feet between patients with unilateral plantar heel pain and healthy individuals, and to determine the relationship between topographical pressure maps, pain intensity, disability, and fascia thickness.
- METHODS: Thirty-five patients with unilateral plantar heel pain and 35 matched healthy controls participated in this cross-sectional, case-control study. Pressure pain thresholds (PPTs) were assessed over 7 plantar locations on each foot. Topographical pressure pain sensitivity maps of the plantar region were generated using the averaged PPT of each assessed point. Pain and related disability were assessed with a numeric pain-rating scale (0-10) and the Foot and Ankle Ability Measure, respectively. Plantar fascia thickness was measured via ultrasound. All outcomes were obtained by an assessor blinded to the participants' condition.
- **RESULTS:** Topographical pressure sensitivity maps revealed lower bilateral PPTs in patients with plantar heel pain compared to healthy controls, and a higher PPT on the calcaneus bone (*P*<.01). Women had lower PPTs than men in all areas (*P*<.001). Individuals with plantar heel pain also had thicker fascia, but only on the affected side, compared to healthy controls. Higher pressure pain sensitivity in the foot was associated with higher pain intensity at first step in the morning and thicker fascia at the calcaneus bone.
- CONCLUSION: People with unilateral plantar heel pain had generalized bilateral pressure pain sensitivity in the plantar region of the foot. Greater pain intensity and fascia thickness were associated with higher pressure pain sensitivity in people with plantar heel pain.
- LEVEL OF EVIDENCE: Case-control study, level
 J Orthop Sports Phys Ther 2019;49(9):640-646.
 Epub 26 Mar 2019. doi:10.2519/jospt.2019.8813
- KEY WORDS: feet, plantar heel pain, pressure pain, sensitization

beginning of a workout.⁵ There is current debate about the proper term for this condition, as there is evidence showing the absence of inflammation and the presence of degenerative changes in the plantar fascia.¹³ Therefore, this condition may be better referred to as plantar fasciopathy²¹ or plantar heel pain.¹⁵ Prevalence of plantar heel pain ranges from 8% to 15% in athletic people²⁵ and from 4% to 7% within the general population, depending on the individual's age.^{7,10}

Plantar fascia thickness may play a role in the condition, because it is associated with symptoms and its changes are positively associated with improvement in pain after treatment in individuals with plantar heel pain.15 Nevertheless, other studies have investigated nociceptive processing in this population by assessing pressure pain sensitivity, though with conflicting results. Rose et al22 observed that individuals with plantar heel pain exhibited higher sensitivity to pressure pain over the medial calcaneal and medial plantar nerves, whereas Saban and Masharawi²³ did not find differences in pressure pain threshold (PPT) on the calcaneal bone between patients and healthy controls. Fernández-Lao et al9 recently found that

Escuela Internacional de Doctorado, Universidad Rey Juan Carlos, Móstoles, Spain. ²Department of Physical Therapy, Occupational Therapy, Rehabilitation and Physical Medicine, Universidad Rey Juan Carlos, Alcorcón, Spain. ³Cátedra de Investigación y Docencia en Fisioterapia, Terapia Manual y Punción Seca, Universidad Rey Juan Carlos, Alcorcón, Spain. ⁴Sport Sciences, Department of Health Science and Technology, Aalborg University, Aalborg, Denmark. ⁵Department of Radiology, Rehabilitation and Physical Therapy, Universidad Complutense de Madrid, Madrid, Spain. ⁶Instituto de Investigación Sanitaria del Hospital Clínico San Carlos, Madrid, Spain. The study design was approved by the Universidad Rey Juan Carlos Ethics Committee (URJC051220160022017). No funds were received for this study. The authors certify that they have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the article. Address correspondence to Dr César Fernández-de-las-Peñas, Facultad de Ciencias de la Salud, Universidad Rey Juan Carlos, Avenida de Atenas s/n, 28922 Alcorcón, Madrid, Spain. E-mail: cesar.fernandez@urjc.es © Copyright ©2019 Journal of Orthopaedic & Sports Physical Therapy

individuals with plantar heel pain showed widespread pressure hypersensitivity compared to healthy people.

Previous studies have analyzed pressure pain sensitivity over a single point in the same area, most likely explaining contradictory findings. Recently developed topographical pressure pain sensitivity maps offer a new imaging modality for assessing the distribution of sensitivity to pain.4 The application of topographical pressure pain sensitivity maps could contribute to a better understanding of pain processing in musculoskeletal pain conditions, by delineating spatial heterogeneity and differences in pressure pain sensitivity.1 For instance, topographical pressure pain sensitivity maps of the foot revealed that women with fibromyalgia syndrome and foot pain had generalized pressure pain sensitivity in the foot compared to women with fibromyalgia syndrome without foot pain and healthy women, and that there is a heterogeneous spatial distribution of pressure pain sensitivity on the foot.26 Because pain symptoms are usually restricted to some areas of the foot in plantar heel pain, topographical pressure pain sensitivity maps may provide relevant information about altered nociceptive pain processing in this condition. Therefore, the aims of this study were (1) to investigate the differences in topographical pressure pain sensitivity maps of the feet between participants with unilateral plantar heel pain and healthy controls; and (2) to determine the relationships between topographical pressure maps, pain intensity, related disability, and fascia thickness in individuals with plantar heel pain. We hypothesized that the topographical distribution of pressure pain sensitivity would be different in individuals with plantar heel pain from that observed in healthy individuals, as delineated by hyperalgesia to pressure pain.

METHODS

Participants

ONSECUTIVE INDIVIDUALS PRESENTing to a physical therapy clinic in Madrid (Spain) with a primary report of heel pain from January 2017 to February 2018 were screened for eligibility. For patients to be eligible, they had to meet the following conditions: (1) clinical diagnosis of plantar heel pain following the clinical practice guidelines from the Academy of Orthopaedic Physical Therapy of the American Physical Therapy Association (ie, insidious onset of sharp pain on the plantar heel surface upon weight bearing after a period of non-weight bearing, heel pain increasing in the morning with the first step after waking up, and pain with palpation of the proximal insertion of the plantar fascia¹⁵), (2) plantar heel pain for more than 3 months, (3) unilateral symptoms, and (4) 18 years of age or older.

Patients were excluded if any of the following criteria were present: (1) a history of surgery to the lower extremity, (2) 2 or more positive neurologic signs consistent with nerve root compression, (3) other causes of heel pain (eg, tarsal tunnel syndrome, arthritis of the foot or ankle, rheumatoid arthritis, peripheral neuropathy), or (4) treatment for the heel received within the previous 6 weeks.

Additionally, age- and sex-matched healthy controls with no history of lower extremity pain, recruited from the general population by local announcements, were also included. Exclusion criteria were the same as for the patient group. The study design was approved by the Universidad Rey Juan Carlos Ethics Committee (URJC051220160022017). All participants signed an informed-consent form prior to their inclusion in the study.

Self-reported Measures

Demographic data included pain history, aggravating and relieving factors, age, sex, height, weight, and body mass index (BMI). An 11-point numeric pain-rating scale, ranging from 0 (no pain) to 10 (maximum pain), was used to determine the pain at first step in the morning, the mean intensity of pain, and the worst and best levels of foot pain experienced during the preceding week.¹²

The Foot and Ankle Ability Measure (FAAM) was used to assess self-reported physical function associated with foot pain.17 It is a 29-item questionnaire consisting of 2 subscales, the activities of daily living subscale (21 items) and the sport subscale (8 items). Answers are scored on a Likert scale ranging from 4 (no difficulty) to 0 (unable to perform the activity). The scores on each item are calculated, and the number of questions answered is multiplied by 4 to obtain the potential score. For example, if all questions are answered, the highest possible score on the activities of daily living subscale is 84, where higher values indicate a higher level of physical functioning. The total score for all items is then divided by the highest possible score and multiplied by 100%. The FAAM is a self-reported outcome for the foot that satisfies all categories of evidence, for example, content validity, construct validity, reliability, and responsiveness.16

Topographical Pressure Pain Sensitivity Maps

Pressure pain threshold, defined as the minimal amount of pressure with which a sensation of pressure first changes to pain, was assessed with an electronic algometer (Somedic AB, Sösdala, Sweden). The algometer was calibrated prior to data collection. The pressure was applied perpendicularly to each point at a rate of approximately 30 kPa/s with a 1-cm² tip. Participants were instructed to press the "stop button" of the algometer as soon as the pressure resulted in pain. The mean of 3 trials on each point was calculated and used for the analysis. A 30-second rest was allowed between trials to avoid temporal summation.¹⁹

Participants were placed in prone, with their feet hanging over the edge of the examination table. They were asked to avoid any analgesic or muscle relaxant 24 hours prior to the examination. Pressure pain thresholds were measured bilaterally over 7 locations (**FIGURE 1**) on each foot by an assessor with 15 years of experience in pressure algometry and

blinded to the individuals' condition, as in previous studies.1 Each location was marked with a pencil: first, third, and fifth metatarsal head bones (points 1-3); the abductor digiti minimi muscle belly (point 4); the flexor digitorum brevis muscle belly (point 5); the abductor hallucis muscle belly (point 6); and the calcaneus bone (point 7). These locations were selected because pain or discomfort is usually reported during weight bearing, in line with previous studies.14,28 High intrarater reliability (intraclass correlation coefficient [ICC] = 0.74-0.97) has been reported for PPT measurements on these locations.28 Saban and Masharawi23 reported smallest real difference values ranging from 98 to 161 kPa in the calcaneus bone between patients with plantar heel pain and healthy controls. Feet were

FIGURE 1. Locations of the assessed pressure pain thresholds on the right foot.

considered affected or nonaffected in the plantar heel pain group and dominant (right) or nondominant (left) in the control group. The order of points was randomized between each participant.

Topographical pressure sensitivity maps of the plantar region were generated using the averaged PPT of each foot point, according to current guidelines.1 This was performed by using an inverse distance-weighted interpolation to obtain a 3-D graphical representation of pressure distribution.24 The inverse distance-weighted interpolation consists of computing PPT to unknown locations by using mean scores from the set of known PPTs and locations.4 Readers are referred to a recent review for more information concerning data interpolation.1

Ultrasonographic Variables

We conducted an ultrasound assessment to obtain quantitative measurements of the plantar fascia. An ultrasound device (MyLab25 Gold; Esaote SpA, Genoa, Italy) and a 12-MHz linear probe were used. Participants were prone, with their feet hanging over the edge of the examination table. The probe was placed over the plantar portion of the heel to get a view of the long axis of the plantar fascia.⁶ The focus was individually adjusted to the depth of the fascia of each participant. The thickness of the sagittal view of the plantar fascia was bilaterally assessed at the following 2 locations: (1) at its proximal end, near its insertion into the calcaneus; and (2) 1 cm from the origin (FIGURE 2). The ultrasonographic assessment was performed by an assessor with 10 years of experience, who was blinded to the participants' condition. Rathleff et al²⁰ reported good intrarater (ICC = 0.77) and interrater (ICC = 0.82)observer reliability for this procedure. These authors20 also observed that changes in plantar fascia thickness larger than 0.6 mm should be considered real changes in thickness and not measurement error.

Statistical Analysis

The sample-size calculations were based on detecting between-group differences of 130 kPa on topographical pressure pain sensitivity maps,23 assuming an SD of 150 kPa, a 2-tailed test, an alpha level of .05, and a desired power of 90%. The estimated desired sample size was calculated to be 29 subjects per group. A dropout percentage of 15% was expected, so 35 participants were included in each group.

Data were analyzed with SPSS Version 21.0 for Windows (IBM Corporation, Armonk, NY). Results are expressed as means, SDs, or 95% confidence intervals. The Kolmogorov-Smirnov test revealed that all quantitative data showed a normal distribution (P>.05). Demographic and clinical characteristics of both groups were compared using unpaired Student t tests and chi-square tests of independence. The Levene test was conducted to analyze the homoscedasticity assumption. A 2-way analysis of covariance (AN-COVA), with side (affected/nonaffected, dominant/nondominant) as the withinsubject factor, group (plantar heel pain or controls) as the between-subject factor, and sex, age, and BMI as covariates, was used to determine differences in ultrasonographic assessments.

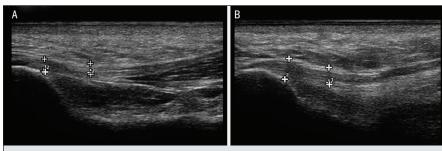


FIGURE 2. Ultrasound measurement of the plantar fascia in (A) a healthy control and (B) a patient with plantar heel pain. The "+" symbol represents caliper measurements.

A multilevel ANCOVA, with side (affected/nonaffected or dominant/nondominant) and points (from 1 to 7) as the within-subject factors, group (plantar heel pain or controls) as the betweensubject variable, and sex, age, and BMI as the main covariates, was applied to detect differences in topographical pressure pain maps. The Bonferroni test was used as a post hoc analysis for determining between-group differences. The Pearson correlation (r) test was used to evaluate the association between PPT, pain intensity, related disability, and fascia thickness within the patient group. In general, the statistical analysis was conducted at a 95% confidence level, except for the ANCOVA, where a Bonferroni-corrected alpha of .0075 (7 points) was considered significant.

RESULTS

ORTY-FIVE INDIVIDUALS WITH PLANtar heel pain were screened for eligibility. Ten (22%) individuals were excluded for the following reasons: bilateral symptoms (n = 4), previous surgery (n = 3), and steroid injection (n = 3). Thirty-five patients (49% women; mean \pm SD age, 42 \pm 10 years) and 35 sex- and age-matched healthy controls (49% women; mean \pm SD age, 41 \pm 11 years) were included. TABLE 1 shows clinical and demographic data of the groups. No differences in demographic variables existed between groups, except for body mass and BMI (P = .04): individuals with plantar heel pain had higher body mass and BMI than healthy controls. Patients with plantar heel pain reported lower physical function, as assessed with the FAAM, compared to healthy controls (*P*<.001).

Ultrasonographic Assessment

There was a significant group-by-side interaction for both the calcaneus (F = 29.286, P<.001) and fascia (F = 10.723, P<.001) points: patients with plantar heel pain had increased fascia thickness in both points (origin and 1 cm from origin) on the affected side compared to the

nonaffected side and healthy controls bilaterally (P<.01 for both) (**TABLE 1**). There were no significant effects of sex (F = 1.118, P = .294), age (F = 1.170, P = .301), or BMI (F = 0.015, P = .903).

Topographical Pressure Pain Sensitivity Maps in Plantar Heel Pain

There were no significant group-by-side (F = 3.503, P = .063) or group-by-side-by-point (F = 0.897, P > .345) interactions. Significant group (F = 11.723, P < .001) and point (F = 14.920, P < .001), but not side (F = 6.072, P = .015), effects were observed. There was a significant effect of sex (F = 12.963, P < .001), but not age (F = 0.276, P = .601) or BMI (F = 0.464, P = .498), in both groups. Post hoc compari-

sons revealed (1) lower bilateral PPTs in individuals with plantar heel pain compared to healthy controls in all assessed points (P<.001), (2) a higher PPT on the calcaneus bone (point 7) than in the remaining foot areas (P<.01) (**FIGURE 3**), and (3) that women had lower PPTs than men in all locations (P<.001). The PPTs of each point in both groups are reported in **TABLE 2**. Topographical pressure pain sensitivity maps of the foot in both groups are presented in **FIGURE 3**.

Topographical Pressure Pain Sensitivity Maps, Pain, Disability, and Fascia Thickness

Within the group of patients with plantar heel pain, we observed significant nega-

TABLE 1

DEMOGRAPHIC AND CLINICAL VARIABLES OF PATIENTS WITH PLANTAR HEEL PAIN AND HEALTHY CONTROLS*

	Plantar Heel Pain (n = 35)	Healthy Controls (n = 35)
Sex, n		
Male	18	18
Female	17	17
Age, y	42 (38, 46)	41 (37, 45)
Height, cm	170 (167, 173)	172 (168, 176)
Body mass, kg	74.5 (69.5, 79.5)	68.0 (63.5, 72.5)
Body mass index, kg/m ²	25.6 (23.6, 27.6)	22.9 (21.7, 24.1)
Affected side, n		NA
Left	18	
Right	17	
History of pain, mo	18.4 (11.7, 25.1)	NA
Intensity of foot pain (NPRS, 0-10)	5.7 (5.0, 6.4)	NA
Pain intensity with first step (NPRS, 0-10)	6.1 (5.4, 6.8)	NA
Worst intensity of foot pain (NPRS, 0-10)	7.6 (6.9, 8.3)	NA
Least intensity of foot pain (NPRS, 0-10)	3.1 (2.5, 3.7)	NA
Ultrasound imaging: calcaneus, cm [†]		
Affected side/dominant side	4.8 (4.6, 5.0)	3.1 (2.9, 3.3)
Nonaffected side/nondominant side	3.8 (3.5, 4.1)	3.2 (3.0, 3.4)
Ultrasound imaging: fascia, cm [†]		
Affected side/dominant side	4.0 (3.8, 4.2)	2.7 (2.4, 3.0)
Nonaffected side/nondominant side	3.1 (2.8, 3.4)	2.6 (2.4, 2.8)
FAAM activities of daily living (0%-100%) [‡]	72.2 (67.0, 77.4)	98.9 (98.1, 99.7)
FAAM sport (0%-100%) [‡]	46.9 (38.6, 55.2)	98.4 (96.8, 100.0)

 $Abbreviations: FAAM, Foot\ and\ Ankle\ Ability\ Measure;\ NA,\ not\ applicable;\ NPRS,\ numeric\ paintaing\ scale.$

^{*}Values are mean (95% confidence interval) unless otherwise indicated.

[†]Significant group-by-side interaction (analysis of covariance, P<.01).

^{*}Significant difference between patients with plantar heel pain and healthy controls (P<.001).

tive moderate associations between pain at first step in the morning and topographical pressure pain sensitivity maps (-0.434<r<-0.343; all, P<.05) and between fascia thickness at the origin and topographical pressure pain sensitivity maps (-0.496 < r < -0.337; all, P < .05): the higher the pain at first step in the morning or the thicker the fascia at the calcaneus bone, the lower the topographical

PPTs, that is, the higher generalized pressure pain sensitivity. There was no other significant association between foot pain, disability, or fascia thickness.

DISCUSSION

E FOUND BILATERAL PRESSURE pain hypersensitivity in the plantar region in patients with chronic plantar heel pain, as assessed by topographical pressure sensitivity maps, supporting our main hypothesis. Pressure pain sensitivity in the plantar area was associated with pain intensity and fascia thickness, but not with related disability. Topographical pressure pain sensitivity maps also revealed heterogeneous distribution of pressure pain sensitivity, depending on the point evaluated, important data to consider in future studies.

We found generalized and bilaterally lower PPTs in the plantar area in individuals with unilateral plantar heel pain. Some studies have previously investigated pressure pain sensitivity in this population, but the results have been conflicting so far. One study reported differences between patients and controls,9 whereas another did not.23 To the best of our knowledge, pressure pain sensitivity maps of the plantar area in patients with plantar heel pain are reported for the first time since Saban and Masharawi23 evaluated pressure pain sensitivity over the calcaneal bone. Discrepancies between studies may be related to the assessed points. Saban and Masharawi23 analyzed PPTs restricted to 4 points over the calcaneus, a bone area, whereas the present study assessed PPTs in different areas throughout the plantar region. Women were characterized by lower PPTs than men, in line with previous studies,3,28 arguing for sex differences in pressure pain sensitivity among patients with unilateral plantar heel pain.

It seems clear that there is a heterogeneous distribution of pressure pain sensitivity depending on the area evaluated, for example, tendon, muscle belly, musculotendinous junction, or bone.1

TABLE 2

PRESSURE PAIN THRESHOLDS ON EACH ASSESSED POINT ON THE FOOT IN PATIENTS WITH PLANTAR HEEL PAIN AND HEALTHY CONTROLS*

	Plantar Heel Pain (n = 35)	Healthy Controls (n = 35)
Point 1 [†]		
Affected/dominant side	273.3 (237.5, 309.1)	423.3 (392.0, 454.6)
Nonaffected/nondominant side	307.9 (272.4, 343.4)	410.5 (387.0, 434.0)
Point 2 [†]		
Affected/dominant side	283.7 (252.6, 314.8)	450.0 (421.2, 479.8)
Nonaffected/nondominant side	323.9 (288.0, 359.8)	473.0 (439.0, 507.0)
Point 3 [†]		
Affected/dominant side	310.0 (275.5, 344.5)	474.2 (448.2, 500.2)
Nonaffected/nondominant side	355.0 (319.2, 390.8)	476.7 (445.8, 507.6)
Point 4 [†]		
Affected/dominant side	307.7 (270.8, 344.6)	502.0 (470.9, 535.1)
Nonaffected/nondominant side	381.6 (348.1, 415.1)	518.9 (491.3, 546.5)
Point 5 [†]		
Affected/dominant side	269.6 (238.5, 300.7)	426.4 (403.0, 449.8)
Nonaffected/nondominant side	331.2 (292.9, 369.5)	429.6 (400.8, 458.4)
Point 6 [†]		
Affected/dominant side	224.4 (199.3, 249.5)	359.3 (341.0, 377.6)
Nonaffected/nondominant side	276.3 (242.9, 309.7)	381.4 (360.3, 402.5)
Point 7 [†]		
Affected/dominant side	330.1 (283.4, 376.8)	566.9 (539.4, 594.4)
Nonaffected/nondominant side	415.9 (374.4, 457.4)	589.9 (551.7, 628.1)

^{*}Values are mean (95% confidence interval) kilopascal.

^{*}Significant difference between patients with plantar heel pain and healthy controls (P<.001).

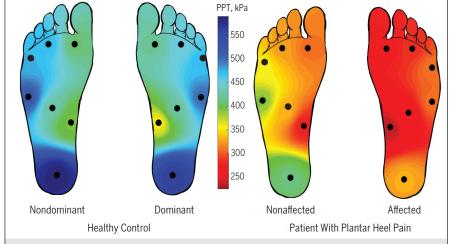


FIGURE 3. Topographical pressure pain sensitivity maps (kilopascal) from the plantar region in healthy controls and patients with plantar heel pain. Abbreviation: PPT, pressure pain threshold.

Further, the topographical pressure pain map of the affected foot was more homogeneous, with an average difference of approximately 61 kPa when compared to the differences of approximately 140, 208, and 209 kPa for the nonaffected foot of people with plantar heel pain and the dominant and nondominant sides of control participants, respectively. Hence, this could be interpreted as a more generalized hyperalgesia on the affected foot in patients with plantar heel pain, although differences were not statistically significant.

We also found topographical differences in pressure pain sensitivity in the plantar area showing that the calcaneus bone exhibited significantly higher PPTs than the remaining points of the foot, in line with previous studies.14,28 The forefoot is more loaded than the heel during walking and direction changes.8 The lower loading pattern for the heel region would explain the higher PPT for the calcaneus bone. The spatial differences in pressure pain sensitivity could also be explained by tissue thickness, the difference in density of nociceptive nerve afferents among muscles, or, in the case of the foot area, repetitive low-load traumas during locomotion.14

The presence of generalized bilateral pressure pain hypersensitivity in patients with unilateral plantar heel pain suggests the presence of sensitization mechanisms in this population, a hypothesis that has been previously proposed.9 It is generally assumed that central sensitization is associated with long-lasting and sustained peripheral noxious input into the central nervous system. The current study also reported that pressure pain hyperalgesia was associated with higher intensity of pain at first step in the morning and greater fascia thickness at its origin, supporting the role of peripheral nociception in pressure pain hyperalgesia in the plantar area in patients with plantar heel pain. These results contrast those of Fernández-Lao et al,9 who found no significant association between pain intensity or fascia thickness and PPT.

One potential explanation for this discrepancy may be that the study by Fernández-Lao et al9 evaluated widespread pressure pain hyperalgesia in distant pain-free areas, whereas our study evaluated PPTs over the plantar area, the symptomatic region in this population. Our results suggest the relevance of tissue damage (fascia) and pain intensity for sensitization mechanisms, suggesting that tissue-based treatment interventions targeting the plantar fascia can be effective for the management of this condition.¹⁵ Interestingly, disability was not associated with topographical pressure pain sensitivity maps, which agrees with a previous systematic review showing that PPTs are not associated with related disability in patients with spinal pain.11 It is most likely that pain and disability represent 2 different constructs in patients with chronic unilateral plantar heel pain.

Our findings have potential clinical implications, for example, ergonomic interventions consisting of foot orthoses, in individuals with plantar heel pain. There is moderate evidence suggesting that foot orthoses are effective for reducing pain in the short and medium term in plantar heel pain; however, the clinical relevance of these changes is still unclear.²⁷ A previous randomized clinical trial found that shock-absorbing insoles were able to decrease pressure pain sensitivity over different points on the plantar area, as well as improve self-reported pain, in a sample of young soccer players.14 The presence of heterogeneous spatial pressure sensitivity observed in the current study could help to improve the design of foot orthoses, with the aim of decreasing peak plantar pressures in individuals with plantar heel pain.

There are some limitations to the present study. First, the cross-sectional design of the study does not permit us to determine any cause-and-effect relationship. Second, patients included in the study sought physical treatment, which could limit the extrapolation of the results. Third, we only assessed PPTs over the plantar area. To further determine the presence of central sensitization, widespread changes should be observed by assessing PPTs over distant, pain-free

CONCLUSION

ATIENTS WITH UNILATERAL PLANTAR heel pain had generalized bilateral pressure pain hypersensitivity in the plantar region, as depicted by topographical pressure pain sensitivity maps. Pressure pain sensitivity in the plantar area was associated with pain intensity and fascia thickness, but not with disability or foot posture.

KEY POINTS

FINDINGS: Patients with unilateral plantar heel pain had generalized bilateral pressure pain sensitivity in the plantar region, as depicted by topographical pressure pain sensitivity maps. Sensitivity was associated with pain intensity and fascia thickness, but not with disability or foot posture.

IMPLICATIONS: Our results support the presence of generalized sensitization in individuals with plantar heel pain, which could influence treatment plans. CAUTION: The generalizability of the results may be limited, as the study design does not permit the determination of a cause-and-effect relationship.

REFERENCES

- 1. Alburguerque-Sendín F, Madeleine P, Fernándezde-las-Peñas C, Camargo PR, Salvini TF. Spotlight on topographical pressure pain sensitivity maps: a review. J Pain Res. 2018;11:215-225. https://doi. org/10.2147/JPR.S135769
- 2. Alvarez-Nemegyei J, Canoso JJ. Heel pain: diagnosis and treatment, step by step. Cleve Clin J Med. 2006;73:465-471.
- 3. Binderup AT, Arendt-Nielsen L, Madeleine P. Pressure pain sensitivity maps of the neckshoulder and the low back regions in men and women. BMC Musculoskelet Disord. 2010;11:234. https://doi.org/10.1186/1471-2474-11-234
- 4. Binderup AT, Arendt-Nielsen L, Madeleine P. Pressure pain threshold mapping - a new imaging modality of muscle sensitivity to pain

- [abstract]. 2008 Annual IEEE Student Paper Conference; February 15-26, 2008; Aalborg, Denmark.
- **5.** Buchbinder R. Clinical practice. Plantar fasciitis. *N Engl J Med*. 2004;350:2159-2166. https://doi. org/10.1056/NEJMcp032745
- Chen CK, Lew HL, Chu NC. Ultrasound-guided diagnosis and treatment of plantar fasciitis. Am J Phys Med Rehabil. 2012;91:182-184. https://doi. org/10.1097/PHM.0b013e3182412187
- Dunn JE, Link CL, Felson DT, Crincoli MG, Keysor JJ, McKinlay JB. Prevalence of foot and ankle conditions in a multiethnic community sample of older adults. *Am J Epidemiol*. 2004;159:491-498. https://doi.org/10.1093/aje/kwh071
- Eils E, Streyl M, Linnenbecker S, Thorwesten L, Völker K, Rosenbaum D. Characteristic plantar pressure distribution patterns during soccer-specific movements. Am J Sports Med. 2004;32:140-145. https://doi. org/10.1177/0363546503258932
- Fernández-Lao C, Galiano-Castillo N, Cantarero-Villanueva I, Martín-Martín L, Prados-Olleta N, Arroyo-Morales M. Analysis of pressure pain hypersensitivity, ultrasound image, and quality of life in patients with chronic plantar pain: a preliminary study. Pain Med. 2016;17:1530-1541. https://doi.org/10.1093/pm/pnv022
- Hill CL, Gill TK, Menz HB, Taylor AW. Prevalence and correlates of foot pain in a populationbased study: the North West Adelaide health study. J Foot Ankle Res. 2008;1:2. https://doi. org/10.1186/1757-1146-1-2
- 11. Hübscher M, Moloney N, Leaver A, Rebbeck T, McAuley JH, Refshauge KM. Relationship between quantitative sensory testing and pain or disability in people with spinal pain—a systematic review and meta-analysis. Pain. 2013;154:1497-1504. https://doi.org/10.1016/j. pain.2013.05.031
- Jensen MP, Turner JA, Romano JM, Fisher LD. Comparative reliability and validity of chronic pain intensity measures. *Pain*. 1999;83:157-162.

- https://doi.org/10.1016/S0304-3959(99)00101-3
- Lemont H, Ammirati KM, Usen N. Plantar fasciitis: a degenerative process (fasciosis) without inflammation. J Am Podiatr Med Assoc. 2003;93:234-237. https://doi. org/10.7547/87507315-93-3-234
- 14. Madeleine P, Hoej BP, Fernández-de-las-Peñas C, Rathleff MS, Kaalund S. Pressure pain sensitivity changes after use of shock-absorbing insoles among young soccer players training on artificial turf: a randomized controlled trial. J Orthop Sports Phys Ther. 2014;44:587-594. https://doi. org/10.2519/jospt.2014.5117
- Martin RL, Davenport TE, Reischl SF, et al. Heel pain—plantar fasciitis: revision 2014. J Orthop Sports Phys Ther. 2014;44:A1-A33. https://doi. org/10.2519/jospt.2014.0303
- Martin RL, Irrgang JJ. A survey of self-reported outcome instruments for the foot and ankle. J Orthop Sports Phys Ther. 2007;37:72-84. https:// doi.org/10.2519/jospt.2007.2403
- 17. Martin RL, Irrgang JJ, Burdett RG, Conti SF, Van Swearingen JM. Evidence of validity for the Foot and Ankle Ability Measure (FAAM). Foot Ankle Int. 2005;26:968-983. https://doi. org/10.1177/107110070502601113
- Menz HB, Jordan KP, Roddy E, Croft PR. Characteristics of primary care consultations for musculoskeletal foot and ankle problems in the UK. Rheumatology (Oxford). 2010;49:1391-1398. https://doi.org/10.1093/rheumatology/keq092
- Nie H, Arendt-Nielsen L, Andersen H, Graven-Nielsen T. Temporal summation of pain evoked by mechanical stimulation in deep and superficial tissue. J Pain. 2005;6:348-355. https://doi. org/10.1016/j.jpain.2005.01.352
- Rathleff MS, Moelgaard C, Olesen JL. Intraand interobserver reliability of quantitative ultrasound measurement of the plantar fascia. *J Clin Ultrasound*. 2011;39:128-134. https://doi. org/10.1002/jcu.20787
- **21.** Rompe JD. Plantar fasciopathy. Sports Med Arthrosc Rev. 2009;17:100-104. https://doi.

- org/10.1097/JSA.0b013e3181a3d60e
- 22. Rose JD, Malay DS, Sorrento DL. Neurosensory testing of the medial calcaneal and medial plantar nerves in patients with plantar heel pain. J Foot Ankle Surg. 2003;42:173-177. https://doi.org/10.1016/S1067-2516(03)70025-8
- Saban B, Masharawi Y. Pain threshold tests in patients with heel pain syndrome. Foot Ankle Int. 2016;37:730-736. https://doi. org/10.1177/1071100716642038
- 24. Shepard D. A two-dimensional interpolation function for irregularly-spaced data. In: Blue RB, Rosenberg AM, eds. Proceedings of the 1968 23rd ACM National Conference. New York, NY: Association for Computing Machinery; 1968:517-524.
- 25. Taunton JE, Ryan MB, Clement DB, McKenzie DC, Lloyd-Smith DR, Zumbo BD. A retrospective case-control analysis of 2002 running injuries. Br J Sports Med. 2002;36:95-101. https://doi.org/10.1136/bjsm.36.2.95
- 26. Tornero-Cabailero MC, Salom-Moreno J, Cigarán-Méndez M, Morales-Cabezas M, Madeleine P, Fernández-de-las-Peñas C. Muscle trigger points and pressure pain sensitivity maps of the feet in women with fibromyalgia syndrome. Pain Med. 2016;17:1923-1932. https://doi.org/10.1093/pm/pnw090
- Whittaker GA, Munteanu SE, Menz HB, Tan JM, Rabusin CL, Landorf KB. Foot orthoses for plantar heel pain: a systematic review and metaanalysis. *Br J Sports Med*. 2018;52:322-328. https://doi.org/10.1136/bjsports-2016-097355
- 28. Xiong S, Goonetilleke RS, Jiang Z. Pressure thresholds of the human foot: measurement reliability and effects of stimulus characteristics. *Ergonomics*. 2011;54:282-293. https://doi.org/10.1080/00140139.2011.552736



NOTIFY JOSPT of Changes in Address

Please remember to let *JOSPT* know about **changes in your mailing address**. The US Postal Service typically will not forward second-class periodical mail. Journals are destroyed, and the USPS charges *JOSPT* for sending them to the wrong address. You may change your address online at **www.jospt.org**. Visit **Info Center** for **Readers**, click **Change of Address**, and complete the online form. We appreciate your assistance in keeping *JOSPT*'s mailing list up to date.

PRISCILLA VIANA SILVA, PT, MSc1 • LEONARDO OLIVEIRA PENA COSTA, PT, PhD1
CHRIS G. MAHER, PT, PhD2 • STEVEN J. KAMPER, PT, PhD23 • LUCÍOLA DA CUNHA MENEZES COSTA, PT, PhD1

The New Agenda for Neck Pain Research: A Modified Delphi Study

eck pain is one of the most prevalent and disabling health conditions, with substantial impacts on public health.^{6,26} The latest Global Burden of Disease¹⁶ study demonstrated that neck pain is the sixth most burdensome health condition worldwide in terms of years lived with disability. Costs related to neck pain are rising, due largely to extended work absenteeism and usage of health care services.^{3,5,6,9,17}

Despite the high prevalence of neck pain, the research priorities in this area remain unclear with regard to the gaps that need to be addressed in future research.¹¹ The Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders⁷ conducted a best-evidence synthesis identifying research gaps in the neck pain field, based on methodological biases, through a criti-

cal review of the neck pain literature. The authors inferred research priorities based on their view of gaps in the neck pain literature; they did not directly survey researchers as to their perceived neck pain research priorities.^{13,22,24}

Increasingly, the Delphi technique has been used to identify research priorities in several health care areas, including nursing and midwifery,²⁸ emergency medical

- BACKGROUND: Though a large amount of research on neck pain has been conducted, no coordinated agenda has identified and addressed high-priority research questions.
- OBJECTIVES: To identify and rank the neck pain research priorities of neck pain researchers.
- METHODS: A total of 400 experts in the field of neck pain were invited to participate in this modified Delphi study. The study was conducted in 3 rounds. The first round aimed to identify the most important relevant questions that neck pain researchers should address. These questions were then categorized and ranked during the second and third rounds.
- RESULTS: A total of 117 experts agreed to participate (29% response rate). A total of 15 neck pain research priorities were identified. The top 5 research priorities were to (1) establish effective-
- ness and cost-effectiveness of available treatments for neck pain, (2) translate research evidence into clinical settings, (3) identify the effectiveness of education and self-care in prevention and treatment of neck pain, (4) identify causal factors in the development of neck pain, and (5) define the natural course and prognostic factors in people with neck pain.
- **CONCLUSION:** A new research-priority agenda was developed through a consensus process from a group of neck pain researchers. This agenda can be used as a guide for researchers and funding agencies to ensure that future research addresses the most important research questions in this area. *J Orthop Sports Phys Ther* 2019;49(9):666-674. Epub 10 Jul 2019. doi:10.2519/jospt.2019.8704
- KEY WORDS: cervical, judgment, spine

services,³⁷ respiratory disorders,² and low back pain (LBP) in primary care.10 The Delphi process is a systematic research technique to collate different opinions from a group of experts on a specific area and create a consensus. 13,20 Furthermore, research agendas encourage investigators and funding agencies to focus on specific questions and thereby improve the relevance and impact of research in the area.^{2,10,18,37} To date, there has been no Delphi study summarizing the views of neck pain experts regarding which research questions should be prioritized. The aim of this study was to identify research priorities in the neck pain field using a modified Delphi technique.

METHODS

Study Design

3-ROUND, INTERNET-BASED, MODIfied Delphi study was conducted. The process ensured that participants remained anonymous throughout the study. The Ethics Committee of the Universidade Cidade de São Paulo approved the study (number 1.294.787).

Participants

Based on similar studies, this study achieved consensus using a sample of about 80 participants. ^{1,8,10,30,33} Predicting an estimated response rate of 20%, we invited 400 experts in neck pain research to participate in this modified Delphi study.

¹Masters and Doctoral Programs in Physical Therapy, Universidade Cidade de São Paulo, São Paulo, Brazil. ²School of Public Health, University of Sydney, Camperdown, Australia. ³Centre for Pain, Health and Lifestyle, Sydney, Australia. The study was approved by the Ethics Committee of the Universidade Cidade de São Paulo (number 1.294.787). The study was funded by São Paulo Research Foundation project grants 2016/14347-0 and 2015/21628-3. The authors certify that they have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the article. Address correspondence to Dr Priscilla Viana Silva, Rua Cesario Galeno 448, Tatuapé, São Paulo, SP 03071-000 Brazil. E-mail: pviana.fisio@gmail.com ® Copyright ©2019 *Journal of Orthopaedic & Sports Physical Therapy*®

Because there is no generally accepted definition of the term *expert*, we identified experts in neck pain research through searches on the Expertscape website (http://expertscape.com). Expertscape uses the number of published papers indexed in MEDLINE, year of publication, type of publication, the journal in which the paper was published, and the order of authorship to score and rank researchers in particular fields. The search was performed in March 2015 using the search terms "neck pain," "neck injuries," and "whiplash injuries."

To supplement the Expertscape search, neck pain researchers were identified from authors of systematic reviews and randomized controlled trials published over the last 5 years in journals indexed in PubMed (https://www.ncbi.nlm.nih.gov/ pubmed). This search (APPENDIX A, available at www.jospt.org) was also performed in March 2015 using the same terms used in the Expertscape search. Articles not relevant to neck pain, neck injuries, and whiplash injuries were excluded. All authors from identified articles were selected for potential inclusion in the study. Authors who appeared at least twice in these searches were automatically selected to participate. As this criterion was insufficient to reach 400 participants, we randomly selected a number of authors who appeared just once in these searches. Further, authors who could not be contacted via e-mail were replaced by authors who appeared just once in the PubMed search.

Modified Delphi Procedures

The classic Delphi technique involves open-ended questions in the first-round questionnaire and the use of as many rounds as necessary to achieve consensus. For this study, 2 modifications were made: (1) adding the LBP research agenda to the first-round questionnaire, which previously only included the open-ended questions, and (2) having a pre-established number (3 rounds) of questionnaires.

The procedures and the questionnaire used in each round were pilot tested by a

group of researchers, who completed the questionnaire on their own and provided feedback on its content and readability. Questions were revised as needed; once finalized, the survey was converted for web completion using SurveyMonkey software (https://pt.surveymonkey.com/?) and sent to the researchers.

Participants were invited by e-mail, which included an explanatory statement about the study, a consent form, and a link to the first round of the study. Each round was accessible for 4 weeks. Reminders were sent to participants who did not respond. At the beginning of the first and second rounds, all participants filled out a sociodemographic questionnaire, which captured their age, sex, nationality, employment, highest academic degree, and professional background. In order to avoid our invitation e-mails from SurveyMonkey being directed to spam, we also sent e-mails to participants through a personal e-mail account. Based on the Delphi technique's evidence-based recommendation, we specified a rate-of-agreement threshold of 70% in each round.22,36

First Round

Participants were asked to list up to 5 topics in response to the following question: "What are the most important primary care-relevant research questions you would like answered about neck pain?" The development of participants' priorities for the next round was conducted by aggregating responses to the first-round question, according to their similarity. In order to ensure that potentially relevant priorities were not missed, LBP research priorities formulated during an international conference in 200910 were presented to the participants only in the first round. We asked participants to indicate whether each of the 25 research questions from the LBP research-priority list was exclusive to LBP, exclusive to neck pain, could be considered for LBP and neck pain, or should not be considered for either. Low back pain priorities were not presented again, because the purpose of subsequent rounds was to rank the neck pain research priorities already identified. The first round was divided in 3 parts: (1) demographic data, (2) the list of 5 neck pain topics that each participant considered important, and (3) the LBP research agenda. In this round, the participants were not able to move forward or backward in the survey.

Second Round

In the second round, all candidate responses from open-ended questions of the first round were presented to the participants. The participants were asked to rate the importance of each item on a 6-point Likert scale, ranging from 0 (not at all important) to 5 (very important). No written descriptors were attached to the other numbers on the scale. The participants were also asked whether there were any missing priorities from the list, any priority listed should be excluded from the list, multiple priorities listed should be collapsed into one, and the wording of priorities should be edited. They were also asked to justify their answer where they had suggested adding, excluding, or collapsing priorities.

Third Round

In the third round, the 15 highest rated responses from the second round were presented. The participants were asked to rank all responses, from 1 (highest priority) to 15 (lowest priority). For the analysis of this ranking, all items were coded from 1 (lowest priority) to 15 (highest priority). In this round, the order in which the research priorities were presented to the participants was randomized to avoid the order of appearance influencing the rankings participants chose.

Statistical Analysis

Data analysis was presented descriptively for each round. For the first round, the open-ended questions were analyzed qualitatively, and the LBP research priorities were analyzed with frequency distributions. For the second round, the mean \pm SD importance score from the Likert scale was calculated and used to rank each priority. Means and SDs were also

used in the third round to rank all items according to the changes made in the neck pain items in the second round.10 The final ranking was created according to the mean scores.

RESULTS

Identifying Experts (Expertscape and PubMed Searches)

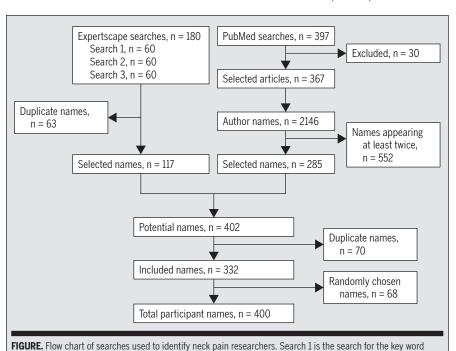
SEARCH ON THE EXPERTSCAPE WEBsite was conducted for each key word: "neck pain," "neck injuries," and "whiplash injuries." The searches identified 180 names (60 per search), 63 of which were duplicates, leaving 117 neck pain experts. The search conducted in PubMed used the same 3 search terms, plus the terms "randomized controlled trial" and "systematic review," filtered by "humans" and "last 5 years" (2010-2015). The PubMed search retrieved a total of 397 articles, of which 30 were excluded because they were not relevant to neck pain. The authors of the remaining 367 selected articles were extracted (n = 2146), 552 appeared at least twice, and after duplicates were excluded, 285 names were selected. To finalize the list of 400 potential participants, we randomly chose 70 names on the list of authors who appeared only once in the 367 selected articles. Of all respondents, 8 (7%) were identified only through Expertscape, 69 (59%) only through PubMed, and 40 (34%) through both databases.

Participants

Of the 400 researchers invited (FIGURE), 117 (29%) participated in at least 1 of the 3 rounds (89 in the first round, 88 in the second round, and 60 in both rounds). Only researchers who participated in the previous rounds were invited for the third round. A total of 117 participants who answered questions in the first or second round were invited to the final round. From these, 91 (78%) participated. Characteristics of the study sample are described in TABLE 1 and in APPENDIX B (available at www.jospt.org). There were no substantial differences in participant characteristics for all rounds.

First Round

We identified 23 candidate priorities for neck pain research that were presented in the second round (TABLE 2).



"neck pain," search 2 is for "neck injuries," and search 3 is for "whiplash injuries."

For the LBP research priorities, we wanted to know whether there would be any differences between LBP and neck pain research agendas. We asked participants to indicate whether they believed each priority from the LBP agenda was exclusively for LBP, exclusively for neck pain, could be considered for LBP and neck pain, or should not be considered for LBP or neck pain. The majority of LBP priorities were considered applicable to both LBP and neck pain. Those who endorsed both LBP and neck pain ranged from 57% to 70% (TABLE 3). Therefore, no LBP priorities needed to be added in the second round.

Second Round

The 23 neck pain research topics identified in the first round were ranked in order of importance by participants, with the highest values corresponding to more important research priorities (from O [not at all important] to 5 [very important]). The lowest mean value of all 23 neck pain topics from the first round was 3.3 points. This means that the participants considered all the topics important. We also asked whether there were any priorities missing from the list or whether any priority listed should be changed. Based on this, 8 of the 23 items were incorporated into other research priorities, leaving 15 final items. In addition, adjustments were made to the explanatory texts of the 15 remaining research priorities to improve readability.

Third Round

In the third round, participants ranked the 15 research priorities from 1 (lowest priority) to 15 (highest priority). The priorities are ordered by mean priority score in TABLE 4.

DISCUSSION

Statement of Main Findings

HE AIM OF THIS STUDY WAS TO achieve consensus on an agenda of neck pain research priorities, using a Delphi process involving researchers

in the neck pain field.^{13,15,18,31} This study identified 15 research priorities in the field of neck pain. The top 5 research priorities were to (1) establish effectiveness and cost-effectiveness of available treatments for neck pain, (2) translate research evidence into clinical settings, (3) establish the effectiveness of education and self-care in prevention and treatment of neck pain, (4) identify causal factors in the development of neck pain, and (5) define the natural course and prognostic factors in people with neck pain.

Findings in the Context of Other Literature

The only previous study⁷ to develop a list of neck pain research priorities aimed to raise awareness of the gaps that needed to be investigated using a best-evidence synthesis. In contrast, our study aimed to compile the views of neck pain researchers to create a neck pain research agenda. The goal of the agenda is to highlight the gaps in the neck pain field by ensuring that the most important questions are addressed preferentially.

Most of the 15 research priorities identified in this modified Delphi study were also listed in the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders study.⁷ That the neck pain research priorities identified in the present study are similar to those identified in the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders study⁷ may reflect (1) a lack of progress in research targeting these priorities, (2) that the priorities were ignored by funders and researchers, or (3) the time it can take for research findings to reach an audience.

Strengths of This Study

The major strength of this study lies in the modified Delphi methodology. The anonymity between the participants and the feedback within the rounds are characteristics of the technique. In our study, anonymity minimized interactions within the sample in an open setting, such that researchers were unable

TABLE 1

CHARACTERISTICS OF THE PARTICIPANTS*

	All Rounds	First Round	Second Round	Third Round
Variable	(n = 117)	(n = 89)	(n = 88)	(n = 91)
Sex (male), n (%)	66 (56)	49 (55)	47 (53)	46 (50.5)
Age, y	49 ± 11.1	48 ± 12.1	49 ± 9.9	49 ± 9.5
Professional background, n (%)				
Physician	12 (10)	9 (10)	8 (9)	6 (7)
Chiropractor	17 (14.5)	12 (13)	13 (15)	14 (15)
Psychologist	8 (7)	6 (7)	7 (8)	7 (8)
Physical therapist	60 (51)	49 (55)	48 (54.5)	44 (48)
Epidemiologist	17 (14.5)	14 (16)	14 (16)	13 (14)
Physiologist	4 (3)	3 (3)	4 (4.5)	3 (3)
Title/position or education, n (%)				
Assistant Professor	3 (3)	8 (9)	11 (12.5)	8 (9)
Associate Professor	33 (28)	20 (22)	21 (24)	21 (23)
Professor	34 (29)	28 (31)	25 (28)	23 (25)
Statistical Consultant	3 (3)	2 (2)	1(1)	1(1)
Masters degree	6 (5)	1(1)	2 (2)	2 (2)
PhD degree	3 (3)	10 (11)	5 (6)	6 (7)
PhD student	13 (11)	3 (3)	5 (6)	2 (2)
Research Fellow	2 (2)	2 (2)	2 (2)	1(1)
Research Assistant	3 (3)	1(1)	1(1)	3 (3)
Researcher	9 (8)	4 (4)	3 (3)	3 (3)
Senior Researcher	4(3)	4 (4)	7 (8)	8 (9)
Years treating neck pain patients, n (%)				
Not a clinician	36 (31)	25 (28)	26 (29.5)	25 (27)
Clinician (do not treat neck pain patients)	7 (6)	3 (3)	7 (8)	7 (8)
1-5	9 (8)	8 (9)	7 (8)	7 (8)
5-10	12 (10)	9 (10)	8 (9)	7 (8)
10-15	10 (9)	10 (11)	11 (12.5)	11 (12)
>15	42 (36)	34 (38)	29 (33)	26 (29)
Currently working in neck pain research, n (%)	111 (95)	84 (94)	82 (93)	78 (86)
Years of experience in neck pain research	13 ± 7	12.5 ± 7.8	13 ± 7.0	13 ± 7.0
Researchers' most important funding sources, n (%)				
Not a researcher	1(1)	1(1)	0 (0)	1(1)
Nongovernmental foundation	7 (6)	27 (30)	28 (32)	1(1)
Private industry	4(3)	8 (9)	10 (11)	9 (10)
Primary care research funding	3 (3)	20 (22.5)	20 (23)	1(1)
Government research institute	18 (15)	55 (62)	43 (49)	42 (46)
Other	17 (14.5)	15 (17)	10 (11)	7 (8)
Continents, n (%)				
Asia [†]	5 (4)	3 (3)	3 (3)	3 (3)
Europe [‡]	59 (50)	47 (53)	50 (57)	43 (47)
America§	28 (24)	20 (22.5)	20 (23)	21 (23)
Oceania (Australia)	23 (20)	18 (20)	14 (16)	15 (16)

^{*} $Values~are~mean \pm SD~unless~otherwise~indicated.$

[†]Countries include Japan, Taiwan, Korea, and Thailand.

[‡]Countries include Denmark, Italy, the Netherlands, Poland, Spain, Belgium, Sweden, France, Germany, the United Kingdom, and Iceland.

[§]Countries include the United States and Canada.

to influence each other's answers.^{13,15,18} Our study preserved anonymity during the 3 rounds, enhancing the credibility of all responses. The controlled feedback

among the rounds is another main characteristic of Delphi studies, providing current information in structured communication throughout the process. 13,29

This study provided all original information gathered from previous rounds.³² The current literature provides varying thresholds for acceptable agreement

TABLE 2

PRELIMINARY NECK PAIN RESEARCH PRIORITIES DEVELOPED DURING THE FIRST ROUND

Priority Description

- The burden of neck pain for the society and individual
 - · The costs of neck pain in terms of impact on individuals' lives, work, and to society as a whole
- 2 Suitable measures for neck pain
 - · Determining the best methods for measuring outcomes for patients with neck pain
- 3 Identifying the risk and causal factors for the development of neck pain
 - · Risk factors and potential causes of neck pain, specified (eg, social determinants, neurogenic, genetic) or not specified
- 4 The influence of biomechanical factors on neck pain development
 - Specific biomechanical causes of neck pain (eg, posture, muscle function, joint dysfunction)
- 5 Defining the natural or clinical course of neck pain
 - The incidence, natural or clinical course, prognosis, and consequences of neck pain, in general and specific populations
- 6 Identifying the prognostic factors for poor outcome for people with neck pain
 - · Factors that predict or determine outcome in people with neck pain, independent of treatment (eg, work factors, psychosocial, lifestyle) or not specified
- The relationship of neck pain to other health conditions and lifestyle factors
 - · Identifying the influence of other health conditions and lifestyle factors on neck pain (eg, headache, rheumatoid arthritis, upper-limb pain, physical activity, and sport)
- Diagnostic tests in the assessment of neck pain
 - · Evaluation strategies for differential diagnosis of neck pain
- The role of imaging in neck pain
 - Whether imaging can contribute to the diagnosis and treatment of neck pain
- 10 Neck pain classification
 - The classification of patients with neck pain, purpose not specified (ie, diagnosis, prognosis, and treatment effect)
- 11 Identifying relevant subgroups of neck pain
 - · Identifying clinical features that can be used to direct treatment decisions. Specifically, identifying which treatment leads to better outcomes in specific individuals with neck pain
- 12 Effectiveness of available treatments
 - · Understanding whether the available treatments for neck pain, such as medication and conservative and physical interventions, are effective
- 13 The cost-effectiveness of treatments for neck pain
 - · Identifying the most cost-effective treatments for neck pain
- 14 Defining the effective dose of available treatments
 - · Identifying the optimal dosage of available interventions for neck pain
- 15 The influence of exercise interventions for neck pain
 - The role and effectiveness of various exercise-based interventions and measures to improve adherence to these interventions
- 16 Manual therapy interventions for neck pain
 - · Determining the effectiveness and safety of manual therapies for neck pain
- 17 Application of the biopsychosocial approach to the management of neck pain
 - The role, effectiveness, and implementation of biopsychosocial and multidisciplinary interventions for neck pain
- 18 The effectiveness of education and self-care in the prevention and treatment of neck pain
 - · Determining the content and effectiveness of education and self-management strategies to manage neck pain and reduce recurrence rates
- 19 Translating research information on neck pain management into primary care clinical practice
 - · Determining the best methods for ensuring that research evidence is used to guide neck pain management
- 20 Management of whiplash-associated disorders
 - · Understanding the prognosis and determining optimal management for people with whiplash-associated disorders
- 21 Prevention of neck pain
 - · Interventions for prevention of neck pain, particularly work-related neck pain
- 22 The role of central nervous system function in neck pain
 - · Brain and neural structure and function in patients with chronic neck pain
- 23 Neck pain patients' beliefs and expectations
 - Patients' beliefs and expectations about their health condition

between participants in Delphi studies. We prespecified a threshold of 70% in each round, which is within the range of agreement-rate values suggested by the literature (51%-80%).^{22-24,29,32,36}

Limitations

The Delphi technique has no specific response rate that is considered acceptable; however, current literature recommends a 70% response rate in order to maintain the representativeness of the results. ^{19,20,24,34,36} The 29% response rate of this study could be considered low^{22,23,36}; however, other studies that sought to identify research priorities using the Delphi technique and other survey-type studies report similarly low response rates. ^{4,8,10,12,14,21,25,30,33,35} Our study used several suggestions of Delphi researchers, such as McKenna, ²⁷ to enhance response rate, including questionnaires

and reminders sent individually. Finally, our final sample mostly comprised male physical therapists, which may have implications in terms of representativeness.

The PubMed search to identify potential participants could be considered another limitation of this study, having been limited to systematic reviews and randomized controlled trials. Authors of studies with other research designs were not considered, as the PubMed search

BP Research Priority	Neither	LBP Only	Both	NP Only
. Can clinically relevant subgroups of LBP be identified?	6 (5.2)	6 (5.2)	72 (62.6)	1 (0.9)
Can we better tailor specific treatments and management strategies to specific subgroups of patients?	7 (7.3)	2 (1.7)	75 (65.2)	1 (0.9)
3. What would be the best strategies for translating research and scientific information into clinical practice?	3 (2.6)	2 (1.7)	79 (68.7)	1(0.9)
4. What are the mechanisms and causes of LBP?	10 (8.7)	2 (1.7)	72 (62.6)	1 (0.9)
5. How do patient and provider opinions, beliefs, and expectations influence outcomes of care for LBP? And how can they be influenced?	6 (5.2)	2 (1.7)	76 (66.1)	1 (0.9)
5. What are the most clinically effective and cost-effective treatments for LBP?	3 (2.6)	1 (0.9)	80 (69.6)	1 (0.9)
7. How can we best organize our primary care services to become more efficient in handling patients with LBP?	4 (3.5)	3 (2.6)	77 (67.0)	1 (0.9)
3. How can we improve self-care strategies?	2 (1.7)	2 (1.7)	80 (69.6)	1 (0.9)
A. What can patients, clinicians, and employers do to prevent significant LBP and associated disability?	3 (2.6)	2 (1.7)	79 (68.7)	1 (0.9)
0. What are effective diagnostic test/evaluation strategies for enabling effective management of LBP?	8 (7.0)	2 (1.7)	74 (64.3)	1 (0.9)
How should LBP be conceptualized and defined?	15 (13.0)	4 (3.5)	66 (57.4)	0 (0.0)
2. What are the most pertinent LBP outcome measures for researchers, clinicians, and patients?	5 (4.3)	2 (1.7)	78 (67.8)	0 (0.0)
3. What can be done to facilitate/encourage patients with LBP to return to work?	9 (7.8)	5 (4.3)	71 (61.7)	0 (0.0)
4. How to reduce the burden of LBP disability?	8 (7.0)	3 (2.6)	74 (64.3)	0 (0.0)
5. What are the course and prognostic factors for patients with nonspecific LBP?	6 (5.2)	4 (3.5)	75 (65.2)	0 (0.0)
6. What is the definition, clinical course, and optimal management of recurrent LBP?	6 (5.2)	4 (3.5)	74 (64.3)	1 (0.9)
7. What can be done to improve the quality of research in LBP?	8 (7.0)	3 (2.6)	74 (64.3)	0 (0.0)
8. How can we improve biopsychosocial interventions in LBP?	5 (4.3)	4 (3.5)	76 (66.1)	0 (0.0)
9. Are workplace interventions efficacious for treating work disability due to LBP?	10 (8.7)	4 (3.5)	71 (61.7)	0 (0.0)
20. What strategies are effective in educating clinicians to improve their effectiveness in communicating and counseling?	10 (8.7)	1 (0.9)	74 (64.3)	0 (0.0)
21. What are the most effective content and method of information provision to current and future primary care patients with LBP?	9 (7.8)	2 (1.7)	74 (64.3)	0 (0.0)
22. Why do some patients with work disability due to LBP continue to work, whereas others do not?	13 (11.3)	5 (4.3)	67 (58.3)	0 (0.0)
23. What impact do benefit systems (such as compensation policies or social security disability) have on LBP?	13 (11.3)	5 (4.3)	67 (58.3)	0 (0.0)
24. What are the (optimal) relationships among employers, clinicians, other stakeholders, and employees to reduce work disability due to LBP?	13 (11.3)	2 (1.7)	70 (60.9)	0 (0.0)
25. What are the processes and determinants for clinicians to sick list a worker with LBP?	17 (14.8)	2 (1.7)	66 (57.4)	0 (0.0)

was only intended to complement the names retrieved from Expertscape. We used systematic reviews and randomized controlled trials as search terms because Expertscape gives higher scores for these study types. In addition, the lack of consensus on the definition of "expert" might also have contributed to inclusion of some participants who did not have

substantial expertise in the field. Nonetheless, we consider this possibility small, given that invited panelists self-selected to participate.

The large proportion of physical therapists in our sample might have been due to the type of studies conducted in primary health care. It is possible that the order of priorities would have been slightly dif-

ferent had more participants from other professional backgrounds participated. Neck pain researchers who chose not to be involved may have a different opinion about the research priorities identified in this study.

Finally, our study aimed to create an agenda from the point of view of researchers in the neck pain field. We be-

TABLE 4 AGENDA FOR PRIMARY CARE RESEARCH ON NECK PAIN				
Neck Pain Research Priority	Mean ± SD*			
 Effectiveness and cost-effectiveness of all available treatments Understanding whether available treatments for neck pain, such as medication, surgery, conservative interventions, manual therapy, and physical and exercise-based interventions, are effective, safe, and cost-effective. This item includes identifying the optimal dosage of available interventions and strategi to improve adherence to these interventions 	10.18 ± 4.17			
 Translating research evidence on neck pain management into the clinical setting Determining the best strategies for ensuring that research evidence is used to guide neck pain management 	9.59 ± 4.28			
 The effectiveness of education and self-care in the prevention and treatment of neck pain Determining the appropriate content and effectiveness of education and self-management strategies to manage neck pain and reduce recurrence rates, including strategies to improve uptake, adherence, and fidelity 	8.82 ± 3.96			
 Identifying the causal factors in the development of neck pain Identifying the risk factors and potential causes of neck pain, for example, psychological predictors, social determinants, neurogenic, genetic, or not specific this item includes specific biomechanical causes of neck pain, for example, posture, muscle function, and joint dysfunction 	8.76 ± 4.21 ed.			
 Defining the natural course and the prognostic factors in people with neck pain The natural or clinical course, prognosis, and consequences of neck pain, in general and specific populations. This item also refers to factors that predict outcomes in people with neck pain, independent of treatment (eg, work factors, psychosocial, lifestyle, physical/biological) or not specified 	8.70 ± 4.07			
Prevention of neck painInterventions for primary or secondary prevention of neck pain, particularly work-related neck pain	8.62 ± 4.32			
 Application of the biopsychosocial approach to the management of neck pain The role, effectiveness, and implementation of biopsychosocial and multidisciplinary interventions for neck pain 	8.58 ± 4.05			
 Suitable core outcome set for neck pain Determining the best methods for measuring outcomes for patients with neck pain (for identifying treatment targets, determining prognosis, measuring adherence and outcomes). This priority includes understanding the measurement properties (reliability, validity, responsiveness, etc) of these measures 	8.48 ± 4.03			
 Identifying relevant subgroups of patients with neck pain Identifying clinical features that can be used to direct treatment decisions and identifying which treatment leads to better outcomes for specific individuals with neck pain. This item includes identifying distinct subpopulations with regard to the diagnosis of and prognosis for patients with neck pain 	8.05 ± 4.75			
 Beliefs and expectations of patients with neck pain Understanding how patients' beliefs and expectations, family, and societal attitudes affect the management and outcomes of neck pain 	7.44 ± 4.04			
 Diagnostic tests in the assessment of neck pain disorders Evaluation of diagnostic tools for differential diagnosis of neck pain with regard to a better understanding of the accuracy, reliability, validity, and predictive ability of these diagnostic tests and tools. This item includes whether imaging can contribute to the diagnosis and treatment of neck pain 	7.33 ± 4.26			
 The role of central nervous system function in chronic neck pain The brain, neural structures, central sensitization, and central nervous system function in patients with chronic neck pain 	7.10 ± 4.39			
 The influence of other health conditions and lifestyle factors on neck pain Identifying the influence of other health conditions on neck pain, for example, headache, rheumatoid arthritis, and upper-limb pain. This item includes ident ing the influence of other nonpain conditions and lifestyle factors on neck pain, such as general health status, diabetes, other chronic disease, physical active and sport 	•			
Management of whiplash-associated disorders Understanding the prognosis and determining optimal management for people with whiplash-associated disorders	6.26 ± 3.80			
 The burden of neck pain for the individual and society Measuring the incidence, prevalence, and costs of neck pain in terms of impact on individuals' lives, work, and society as a whole 	5.40 ± 4.11			
*A higher mean score represents a higher priority.				

lieve that patient and clinician responses would have contributed positively to this research agenda, and the lack of their participation can be considered a limitation of this study. Nevertheless, our study sought to identify the research priorities in neck pain from the perspective of the neck pain researcher. Future studies should focus on taking into account the opinions of both patients and clinicians.

CONCLUSION

HIS RESEARCH AGENDA ON NECK pain can be used to guide future research conducted in the area. We recommend that this information be used to help funders and researchers prioritize resource allocation and design research questions, which will ensure that future research attends to areas of importance and conserves resources. •

KEY POINTS

FINDINGS: This study provides a consensus agenda of the research priorities in the neck pain field.

IMPLICATIONS: The use of this agenda should be encouraged in neck pain research to improve the research quality in this area, filling the gaps that are shown to be more important.

CAUTION: The existence of this agenda does not necessarily mean that the priorities of clinicians and patients are included.

REFERENCES

- 1. Akins RB, Tolson H, Cole BR. Stability of response characteristics of a Delphi panel: application of bootstrap data expansion. BMC Med Res Methodol. 2005;5:37. https://doi. org/10.1186/1471-2288-5-37
- 2. Araújo V, Teixeira PM, Yaphe J, Correia de Sousa J. The respiratory research agenda in primary care in Portugal: a Delphi study. BMC Fam Pract. 2016;17:124. https://doi.org/10.1186/ s12875-016-0512-1
- 3. Borghouts JA, Koes BW, Vondeling H, Bouter LM. Cost-of-illness of neck pain in the Netherlands in 1996. Pain. 1999;80:629-636. https://doi. org/10.1016/S0304-3959(98)00268-1
- **4.** Brenner M, Hilliard C, Regan G, et al. Research priorities for children's nursing in Ireland: a

- Delphi study. J Pediatr Nurs. 2014;29:301-308. https://doi.org/10.1016/j.pedn.2014.01.003
- 5. Carroll LJ, Hogg-Johnson S, Côté P, et al. Course and prognostic factors for neck pain in workers: results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. J Manipulative Physiol Ther. 2009;32:S108-S116. https://doi.org/10.1016/j. jmpt.2008.11.015
- 6. Carroll LJ, Hogg-Johnson S, van der Velde G, et al. Course and prognostic factors for neck pain in the general population: results of the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. J Manipulative Physiol Ther. 2009;32:S87-S96. https://doi. org/10.1016/j.jmpt.2008.11.013
- 7. Carroll LJ, Hurwitz EL, Côté P, et al. Research priorities and methodological implications: the Bone and Joint Decade 2000-2010 Task Force on Neck Pain and Its Associated Disorders. Spine (Phila Pa 1976). 2008;33:S214-S220. https://doi. org/10.1097/BRS.0b013e318164462c
- 8. Chiarotto A, Terwee CB, Deyo RA, et al. A core outcome set for clinical trials on non-specific low back pain: study protocol for the development of a core domain set. Trials. 2014;15:511. https://doi. org/10.1186/1745-6215-15-511
- 9. Cohen SP. Epidemiology, diagnosis, and treatment of neck pain. Mayo Clin Proc. 2015;90:284-299. https://doi.org/10.1016/j. mayocp.2014.09.008
- 10. Costa LCM, Koes BW, Pransky G, Borkan J, Maher CG, Smeets RJ. Primary care research priorities in low back pain: an update. Spine (Phila Pa 1976). 2013;38:148-156. https://doi.org/10.1097/ BRS.0b013e318267a92f
- 11. Côté P, Cassidy JD, Carroll LJ, Kristman V. The annual incidence and course of neck pain in the general population: a population-based cohort study. Pain. 2004;112:267-273. https://doi. org/10.1016/j.pain.2004.09.004
- 12. de Souza FS, Ladeira CE, Costa LOP. Adherence to back pain clinical practice guidelines by Brazilian physical therapists: a cross-sectional study. Spine (Phila Pa 1976). 2017;42:E1251-E1258. https://doi.org/10.1097/ BRS.000000000002190
- 13. Diamond IR, Grant RC, Feldman BM, et al. Defining consensus: a systematic review recommends methodologic criteria for reporting of Delphi studies. J Clin Epidemiol. 2014;67:401-409. https://doi.org/10.1016/j. jclinepi.2013.12.002
- 14. Dibley L, Bager P, Czuber-Dochan W, et al. Identification of research priorities for inflammatory bowel disease nursing in Europe: a Nurses-European Crohn's and Colitis Organisation Delphi survey. J Crohns Colitis. 2017;11:353-359. https://doi.org/10.1093/ecco-jcc/jjw164
- 15. Froud R, Eldridge S, Kovacs F, et al. Reporting outcomes of back pain trials: a modified Delphi study. Eur J Pain. 2011;15:1068-1074. https://doi. org/10.1016/j.ejpain.2011.04.015
- 16. GBD 2016 Disease and Injury Incidence and

- Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 328 diseases and injuries for 195 countries, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. Lancet. 2017;390:1211-1259. https://doi. org/10.1016/S0140-6736(17)32154-2
- 17. Genebra CV, Maciel NM, Bento TPF, Simeão S, Vitta A. Prevalence and factors associated with neck pain: a population-based study. Braz J Phys Ther. 2017;21:274-280. https://doi.org/10.1016/j. bjpt.2017.05.005
- 18. Griffith LE, Hogg-Johnson S, Cole DC, et al. Lowback pain definitions in occupational studies were categorized for a meta-analysis using Delphi consensus methods. J Clin Epidemiol. 2007;60:625-633. https://doi.org/10.1016/j. jclinepi.2006.09.005
- 19. Gupta UG, Clarke RE. Theory and applications of the Delphi technique: a bibliography (1975-1994). Technol Forecast Soc Change. 1996;53:185-211. https://doi.org/10.1016/S0040-1625(96)00094-7
- **20.** Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs. 2000;32:1008-1015. https://doi. org/10.1046/j.1365-2648.2000.t01-1-01567.x
- 21. Hendrick P, Mani R, Bishop A, Milosavljevic S, Schneiders AG. Therapist knowledge, adherence and use of low back pain guidelines to inform clinical decisions - a national survey of manipulative and sports physiotherapists in New Zealand. Man Ther. 2013;18:136-142. https://doi. org/10.1016/j.math.2012.09.002
- **22.** Hsu CC, Sandford BA. The Delphi technique: making sense of consensus. Pract Assess Res Eval. 2007;12:1-8.
- 23. Keeney S, Hasson F, McKenna HP. A critical review of the Delphi technique as a research methodology for nursing. Int J Nurs Stud. 2001;38:195-200. https://doi.org/10.1016/ \$0020-7489(00)00044-4
- 24. Kennedy HP. Enhancing Delphi research: methods and results. J Adv Nurs. 2004;45:504-511. https:// doi.org/10.1046/j.1365-2648.2003.02933.x
- 25. Ladeira CE, Cheng MS, Hill CJ. Physical therapists' treatment choices for non-specific low back pain in Florida: an electronic survey. J Man Manip Ther. 2015;23:109-118. https://doi. org/10.1179/2042618613Y.0000000065
- 26. Lee H, Hübscher M, Moseley GL, et al. How does pain lead to disability? A systematic review and meta-analysis of mediation studies in people with back and neck pain. Pain. 2015;156:988-997. https://doi.org/10.1097/j. pain.0000000000000146
- 27. McKenna HP. The Delphi technique: a worthwhile research approach for nursing? J Adv Nurs. 1994;19:1221-1225. https://doi. org/10.1111/j.1365-2648.1994.tb01207.x
- 28. Monterosso L, Ross-Adjie G, Keeney S. Developing a research agenda for nursing and midwifery: a modified Delphi study. Contemp Nurse. 2015;51:83-95. https://doi.org/10.1080/10 376178.2015.1116372

- Okoli C, Pawlowski SD. The Delphi method as a research tool: an example, design considerations and applications. *Inform Manag.* 2004;42:15-29. https://doi.org/10.1016/j.im.2003.11.002
- Page MJ, Huang H, Verhagen AP, Buchbinder R, Gagnier JJ. Identifying a core set of outcome domains to measure in clinical trials for shoulder disorders: a modified Delphi study. *RMD Open*. 2016;2:e000380. https://doi.org/10.1136/ rmdopen-2016-000380
- Pinnock H, Epiphaniou E, Sheikh A, et al. Developing standards for reporting implementation studies of complex interventions (StaRl): a systematic review and e-Delphi. *Implement Sci.* 2015;10:42. https://doi.org/ 10.1186/s13012-015-0235-z
- **32.** Powell C. The Delphi technique: myths and realities. *J Adv Nurs*. 2003;41:376-382. https://doi.org/10.1046/j.1365-2648.2003.02537.x
- 33. Rodgers M, Booth A, Norman G, Sowden A. Research priorities relating to the debate on assisted dying: what do we still need to know? Results of a modified Delphi technique. BMJ Open. 2016;6:e012213. https://doi.org/10.1136/ bmjopen-2016-012213
- Rowe G, Wright G, Bolger F. Delphi: a reevaluation of research and theory. *Technol Forecast* Soc Change. 1991;39:235-251. https://doi. org/10.1016/0040-1625(91)90039-I
- 35. Stanton TR, Latimer J, Maher CG, Hancock MJ. A modified Delphi approach to standardize low back pain recurrence terminology. Eur Spine

- *J.* 2011;20:744-752. https://doi.org/10.1007/s00586-010-1671-8
- Trevelyan EG, Robinson N. Delphi methodology in health research: how to do it? Eur J Integr Med. 2015;7:423-428. https://doi.org/10.1016/ j.eujim.2015.07.002
- 37. van de Glind I, Berben S, Zeegers F, et al. A national research agenda for pre-hospital emergency medical services in the Netherlands: a Delphi-study. Scand J Trauma Resusc Emerg Med. 2016;24:2. https://doi.org/10.1186/s13049-015-0195-y



CHECK Your References With the *JOSPT* Reference Library

JOSPT has created an EndNote reference library for authors to use in conjunction with PubMed/Medline when assembling their manuscript references. This addition to Author and Reviewer Tools on the JOSPT website in the Author and Reviewer Centers offers a compilation of all article reference sections published in the Journal from 2006 to date as well as complete references for all articles published by JOSPT since 1979—a total of more than 30,000 unique references. Each reference has been checked for accuracy.

This resource is **updated twice a year** on *JOSPT*'s website.

The *JOSPT* Reference Library can be found at: http://www.jospt.org/page/authors/author_reviewer_tools

APPENDIX A

PUBMED SEARCH STRATEGY

Results: 397 articles. The search was conducted on March 23, 2015.

((((("neck pain" AND "last 5 years"[PDat] AND Humans[Mesh])) OR ("neck injuries" AND "last 5 years"[PDat] AND Humans[Mesh])) OR ("whiplash injuries" AND "last 5 years"[PDat] AND Humans[Mesh])) AND "last 5 years"[PDat] AND Humans[Mesh])) AND "last 5 years"[PDat] AND Humans[Mesh])) OR ("systematic review" AND "last 5 years"[PDat] AND Humans[Mesh])) AND "last 5 years"[PDat] AND Humans[Mesh])) Filters: published in the last 5 years; Humans

APPENDIX B

PARTICIPATION BY COUNTRY IN THE STUDY (N = 117)

	n (%)	HDI*	HD Rank*
Country			
Australia	23 (20)	0.939	3
Denmark	13 (11)	0.929	11
Canada	12 (10)	0.926	12
United States	16 (14)	0.924	13
Italy	2 (2)	0.880	28
The Netherlands	9 (8)	0.931	10
Poland	1(1)	0.865	33
Spain	9 (8)	0.891	26
Belgium	6 (5)	0.916	17
Sweden	9 (8)	0.933	7
Korea	2 (2)	0.903	22
France	1(1)	0.901	24
Germany	4(3)	0.936	5
United Kingdom	4(3)	0.922	14
Thailand	1(1)	0.755	83
Iceland	1(1)	0.935	6
Taiwan	1(1)	0.882	25
Japan	1(1)	0.909	19
Missing data	2 (2)		

 $Abbreviations: HD, human\ development; HDI, Human\ Development\ Index.$

^{*}Values are from 2017 (http://hdr.undp.org/en/countries).

VIEWPOINT

ANDREW SPRAGUE, PT. DPT12 • SCOTT EPSLEY, PT3 • KARIN GRÄVARE SILBERNAGEL, PT. ATC, PhD12

Distinguishing Quadriceps Tendinopathy and Patellar Tendinopathy: Semantics or Significant?

J Orthop Sports Phys Ther 2019;49(9):627-630. doi:10.2519/jospt.2019.0611

ou arrive at your clinic and check the schedule, in preparation for a day of patient care. An initial evaluation has been added to your first treatment slot, with a referral from an orthopaedist for "jumper's knee." "I've seen this before," you think to yourself. "Patellar tendinopathy, no question." In preparation, you pull out your patellar tendon loading protocol and make some assumptions about how the patient will present, and how you might approach the shared

decision making for appropriate management. When you begin your assessment, to your surprise, the patient complains of pain in the quadriceps tendon, not in the patellar tendon. What do you do now?

Jumper's knee is not synonymous with patellar tendinopathy.⁴ The term includes patellar tendinopathy and quadriceps tendinopathy.⁴ Patellar tendinopathy has been extensively researched, whereas quadriceps tendinopathy has been largely ignored.^{9,16,18,21} As a result, clinicians may have resorted to treating quadriceps tendinopathy with rehabilitation programs designed for patellar tendinopathy. Although the patellar and quadriceps tendons work in tandem as part of the extensor mechanism of the knee, they have distinct anato-

my and functional roles. As a result, there are probable differences in risk factors, etiology, and response to treatment.

It is time to clinically separate patellar tendinopathy and quadriceps tendinopathy and design more specific rehabilitation programs. In this Viewpoint, we will (1) provide a rationale for distinguishing the 2 clinical entities—patellar tendinopathy and quadriceps tendinopathy—for treatment decision making, and (2) identify areas of research priority in quadriceps tendinopathy.

Anatomical and Biomechanical Differences

The patellar tendon attaches bone to bone, whereas the quadriceps tendon attaches muscle to bone (FIGURE 1). The

patellar tendon connects 2 structures of similar stiffness, whereas the quadriceps tendon connects 2 structures with dramatically different stiffness. Tendon mechanical properties mimic their adjacent structures.² Tendon has greater extensibility (less stiffness) at the region closest to the muscle. Conversely, regions closer to the bone are less extensible (stiffer).

The adjustment of stiffness along a tendon allows for efficient and safe transmission of force from compliant muscle to stiff bone. When landing from a jump, the knee flexes to absorb the impact. Simultaneously, the quadriceps muscle contracts eccentrically to control knee flexion. The quadriceps tendon must act as a shock absorber, lengthening along with the quadriceps. Where materials of different stiffness join, there can be stress concentrations at their interface.19 Consequently, if the tendon was overly stiff close to the muscle and unable to lengthen, then the quadriceps musculotendinous junction and muscle may be at increased risk of injury. Due to the

¹Department of Physical Therapy, University of Delaware, Newark, DE. ²Department of Biomechanics and Movement Science, University of Delaware, Newark, DE. ³Philadelphia 76ers, Philadelphia, PA. This work was supported in part by Promotion of Doctoral Studies I and Florence P. Kendall Doctoral Scholarships from the Foundation for Physical Therapy, by the National Institute of Arthritis and Musculoskeletal and Skin Diseases of the US National Institutes of Health under award number T32HD007490-18, and by an Endowment Scholarship from the University of Delaware Department of Physical Therapy. The authors certify that they have no affiliations with or financial involvement in any organization or entity with a direct financial interest in the subject matter or materials discussed in the article. Address correspondence to Dr Karin Grävare Silbernagel, STAR Health Sciences Complex, 540 South College Avenue, Suite 210W, Newark, DE 19713. E-mail: kgs@udel.edu © Copyright ©2019 Journal of Orthopaedic & Sports Physical Therapy®

VIEWPOINT

difference in attachment sites, the patellar tendon is stiffer than the quadriceps tendon.¹⁴

There are differences in structure between the patellar tendon and quadriceps tendon. The patellar tendon is a relatively linear structure, composed of superficial and deep layers, running in parallel, without direct muscular attachments.3 The superficial layer is a continuation of quadriceps tendon fibers from the rectus femoris.1 Fibers of the deep layer begin at the most distal aspect of the patella and insert, along with the superficial fibers, at the tibial tuberosity. In contrast, the quadriceps tendon is a more complex and variable structure, arising from 4 separate muscles. Typically, the quadriceps tendon has 3 layers: a superficial layer (rectus femoris), intermediate layer (vastus lateralis and medialis), and deep layer (vastus intermedius). However, the number of layers and relative contribution of each muscle are highly variable.24

Interactions between these layers and the surrounding matrix may have implications for the pathogenesis, symptom and imaging presentation, or treatment of quadriceps tendinopathy,²⁰ but have not yet been considered in the literature. Each quadriceps muscle has a unique line of action, subjecting the quadriceps tendon to nonuniform load and shear forces. The force transmitted through the patellar tendon is more uniform. 11,23

Epidemiology of Patellar Tendinopathy and Quadriceps Tendinopathy

Patellar tendinopathy presents as pain at the inferior pole of the patella. Up to 14% of recreational and 45% of elite jumping athletes experience symptoms at any given time.10 Conversely, quadriceps tendinopathy presents as pain at the superior pole of the patella, with symptoms most pronounced with deep knee flexion. The initial onset of symptoms is usually related to an acute incident involving high levels of eccentric quadriceps loading, which occurs, for example, with knee flexion when landing from a rebound in basketball. However, symptoms are typically preceded by a period of excessive load.6 Although few studies have examined the prevalence of quadriceps tendinopathy, the prevalence estimates range from 0.2% to 2% in athletic populations. 10,22 Among athletes with extensor mechanism pain, up to 1 in 4 experience pain at the superior pole of the patella. 10,22

TT P QT RF VI

FIGURE 1. Longitudinal ultrasound images of uninjured patellar and quadriceps tendons. Abbreviations: F, femur; P, patellar, PT, patellar tendon; QT, quadriceps tendon; RF, rectus femoris; TT, tibial tuberosity; VI, vastus intermedius.

Treatment of Patellar Tendinopathy and Quadriceps Tendinopathy: Similarities and Differences

Clinicians and patients are challenged by a lack of scientific evidence to help them make quality decisions when managing quadriceps tendinopathy. In the absence of evidence, understanding the anatomy and biomechanics of the quadriceps tendon can help the clinician tailor a treatment program for quadriceps tendinopathy. In this section, we highlight the common principles for treating both patellar and quadriceps tendinopathy, and provide suggestions for how the clinician might tailor a program for quadriceps tendinopathy (TABLE).

Key Principles: Activity Modification and Graduated Loading All tendinopathies, including patellar and quadriceps tendinopathies, are overuse injuries resulting from tendon overload with inadequate recovery. The primary symptom is load-dependent tendon pain, where greater loads result in a higher degree of pain, during or immediately after activity. Therefore, these injuries may benefit from activity modification.

In addition to pain, tendinopathies are accompanied by changes in tendon structure (tendinosis) and mechanical properties. Thus, tendinopathies benefit from controlled tendon loading programs to reduce pain, promote remodeling, and restore mechanical properties. However, these similarities do not mean that the treatment strategies can be identical for patellar and quadriceps tendinopathies.

Preferentially Loading the Quadriceps Tendon The patellar tendon and quadriceps tendon are not loaded equally throughout knee motion. The quadriceps tendon experiences greater loads than the patellar tendon as the knee moves further into flexion. This relationship is due to an increasing mechanical advantage of the patellar tendon and greater passive tension in the quadriceps muscle as it approaches end range. This may explain why pain in quadriceps tendinopathy is most pronounced in activities that

involve deep knee flexion. Graduated loading programs for quadriceps tendinopathy should include appropriate loading in deep knee flexion. However, bony abnormalities are common, and some patients may experience excess compression from the patella. In highly symptomatic cases, the patient may not tolerate loading in deep knee flexion in the early phases of treatment.

The load generated by the 4 quadriceps muscles causes nonuniform load through the quadriceps tendon. Some areas of the tendon are stress shielded, and areas close to the patella may be compressed. Areas of lower stress and areas of increased compression may be more susceptible to injury. Therefore, additional modifications may be needed, based on the patient's response, to avoid compression and stress shielding when loading the tendon across the region of injury.11 Based on the multidirectional nature of the quadriceps line of action, tibial rotation may preferentially load or unload specific regions. Combining hip extension with deep knee flexion loading may increase forces in the superficial layer of the tendon.

Pain as a Guide for Clinical Decision Making Mild to moderate pain is typically acceptable in patellar tendinopathy treatment protocols. There is no reason to believe this should not be the case for quadriceps tendinopathy. Pain may be a good clinical guide to appropriate tendon loading.¹⁷ Because of the complex struc-

ture of the quadriceps tendon, it is possible for force transfer to occur without force transmission through the pathological region of the tendon. There may be injury-induced alterations in quadriceps muscle function that unload the pathological region.¹³ Therefore, provoking pain during tendon loading may help clinicians identify positions in which force is transmitted through the appropriate part of the tendon. We suggest that pain should not exceed 5/10 on the numeric pain-rating scale (0 is no pain, 10 is the worst pain imaginable) during or immediately after treatment (FIGURE 2).15 Symptoms should subside to baseline levels by the following morning and not increase from week to week. Pain thresholds may need to be modified based on the irritability of the patient.

Addressing Altered Muscle Function Changes in corticospinal excitability to the quadriceps muscle in patients with patellar tendinopathy may alter muscle activation.13 In pilot studies, many individuals with patellar tendinopathy had reduced voluntary activation of the quadriceps. Therefore, we expect that there may be changes in quadriceps muscle function among patients with quadriceps tendinopathy. However, these changes may pose additional problems in quadriceps tendinopathy that are not present in patellar tendinopathy. In patellar tendinopathy, the force from the quadriceps is ultimately transferred through the patella to the patellar tendon, even if this force is diminished. In quadriceps tendinopathy, changes in relative activation of the 4 muscles may underload or stress shield the pathological area. Neuromuscular electrical stimulation or functional electrical stimulation may help offset these changes, augmenting quadriceps activation and ensuring adequate loading of all regions of the tendon.

Restoration of Mechanical Properties Tendinopathy may alter the mechanical properties of tendon and impair performance.^{5,8} One aim of treatment for tendon injuries is to restore mechanical properties, although the clinical goals may be different. Healthy patellar and quadriceps tendons differ in their mechanical properties and may also differ in their response to injury. In patients with unilateral quadriceps tendinopathy, sonoelastography (a noninvasive method of measuring mechanical properties in vivo) has shown that symptomatic quadriceps tendons have lower stiffness in the pathological region than in the uninjured limb. In contrast, individuals with patellar tendinopathy show increased tendon stiffness in the injured limb that correlates with symptom severity.25

Summary

The differences in anatomy, function, and response to injury between patellar tendinopathy and quadriceps tendinopathy warrant clinical distinction. To help clinicians and patients with quadriceps

TABLE Key Principles of Quadriceps Tendinopathy Treatment

- Controlled tendon loading is the central tenet of treatment.
- Activity modification may be necessary to prevent worsening of symptoms and to allow adequate time for the tendon to recover.
- Loading in end-range knee flexion may maximize load in the quadriceps tendon, but caution should be used in the
 presence of bony abnormalities.
- The addition of tibial rotation and/or hip extension with loading exercise may preferentially load different regions of the quadriceps tendon.
- Mild to moderate pain during loading is not detrimental and may help target loading to the pathological region of the tendon.
- Electrical stimulation may be beneficial in restoring quadriceps muscle function and ensuring adequate load across
 the tendon.



- 1. The pain is allowed to reach 5 on the NPRS during the activity.
- The pain after completion of the activity is allowed to reach 5 on the NPRS.
- 3. The pain the morning after the activity should not exceed 5 on the NPRS.
- 4. Pain and stiffness are not allowed to increase from week to week.

FIGURE 2. The pain-monitoring model. Abbreviation: NPRS, numeric pain-rating scale.

VIEWPOINT

tendinopathy make quality decisions, we suggest that future research focus on 3 key areas:

- Investigating the etiology and characteristics of quadriceps tendinopathy, and addressing the regions or layers of the tendon that are most commonly involved (alterations to exercises that preferentially load the most common areas of pathology should be identified and tested)
- Developing quadriceps tendinopathyspecific outcome measures, including measures of symptom severity and tendon mechanical properties, to provide a more complete picture of tendon health
- 3. Conducting clinical trials to ascertain the efficacy of current and proposed treatments so clinicians can design and implement effective, tailored treatment programs

Key Points

- Patellar and quadriceps tendinopathies are often grouped under the umbrella diagnosis of jumper's knee.
- Although the patellar and quadriceps tendons work in tandem as part of the extensor mechanism, they have distinct anatomy and functional roles.
- Quadriceps tendon loading should be performed in deep knee flexion, and additional alterations may be necessary to preferentially load the pathological region.
- Recognition of and research on quadriceps tendinopathy as a distinct diagnosis are needed to improve patient outcomes.

REFERENCES

- Andrikoula S, Tokis A, Vasiliadis HS, Georgoulis A. The extensor mechanism of the knee joint: an anatomical study. Knee Surg Sports Traumatol Arthrosc. 2006;14:214-220. https://doi. org/10.1007/s00167-005-0680-3
- 2. Arruda EM, Calve S, Dennis RG, Mundy K, Baar

- K. Regional variation of tibialis anterior tendon mechanics is lost following denervation. *J Appl Physiol* (1985). 2006;101:1113-1117. https://doi.org/10.1152/japplphysiol.00612.2005
- Basso O, Johnson DP, Amis AA. The anatomy of the patellar tendon. Knee Surg Sports Traumatol Arthrosc. 2001;9:2-5. https://doi.org/10.1007/ s001670000183
- Blazina ME, Kerlan RK, Jobe FW, Carter VS, Carlson GJ. Jumper's knee. Orthop Clin North Am. 1973:4:665-678
- De Vries AJ, Koolhaas W, Zwerver J, et al. The impact of patellar tendinopathy on sports and work performance in active athletes. Res Sports Med. 2017;25:253-265. https://doi.org/10.1080/15438 627.2017.1314292
- Ferretti A. Epidemiology of jumper's knee. Sports Med. 1986;3:289-295. https://doi. org/10.2165/00007256-198603040-00005
- Klauser AS, Miyamoto H, Bellmann-Weiler R, Feuchtner GM, Wick MC, Jaschke WR. Sonoelastography: musculoskeletal applications. *Radiology*. 2014;272:622-633. https://doi.org/10.1148/ radiol.14121765
- Kubo K, Kawakami Y, Fukunaga T. Influence of elastic properties of tendon structures on jump performance in humans. *J Appl Physiol* (1985). 1999;87:2090-2096. https://doi.org/10.1152/ jappl.1999.876.2090
- Larsson ME, Käll I, Nilsson-Helander K. Treatment of patellar tendinopathy—a systematic review of randomized controlled trials. *Knee Surg Sports Traumatol Arthrosc.* 2012;20:1632-1646. https://doi.org/10.1007/s00167-011-1825-1
- Lian ØB, Engebretsen L, Bahr R. Prevalence of jumper's knee among elite athletes from different sports: a cross-sectional study. Am J Sports Med. 2005;33:561-567. https://doi. org/10.1177/0363546504270454
- Maganaris CN, Narici MV, Almekinders LC, Maffulli N. Biomechanics and pathophysiology of overuse tendon injuries: ideas on insertional tendinopathy. Sports Med. 2004;34:1005-1017. https://doi. org/10.2165/00007256-200434140-00005
- 12. Powers CM, Chen YJ, Scher IS, Lee TQ. Multiplane loading of the extensor mechanism alters the patellar ligament force/quadriceps force ratio. *J Biomech Eng*. 2010;132:024503. https://doi. org/10.1115/1.4000852
- Rio E, Kidgell D, Moseley GL, Cook J. Elevated corticospinal excitability in patellar tendinopathy compared with other anterior knee pain or no pain. Scand J Med Sci Sports. 2016;26:1072-1079. https://doi.org/10.1111/sms.12538
- 14. Shani RH, Umpierez E, Nasert M, Hiza EA, Xerogeanes J. Biomechanical comparison of quadriceps and patellar tendon grafts in anterior cruciate ligament reconstruction. *Arthroscopy*. 2016;32:71-75. https://doi.org/10.1016/j.arthro.2015.06.051
- 15. Silbernagel KG, Thomeé R, Eriksson BI, Karlsson

- J. Continued sports activity, using a pain-monitoring model, during rehabilitation in patients with Achilles tendinopathy: a randomized controlled study. *Am J Sports Med.* 2007;35:897-906. https://doi.org/10.1177/0363546506298279
- 16. Simpson M, Smith TO. Quadriceps tendinopathy—a forgotten pathology for physiotherapists? A systematic review of the current evidence-base. Phys Ther Rev. 2011;16:455-461. https://doi.org/10.1179/1743288X11Y.0000000035
- 17. Smith BE, Hendrick P, Smith TO, et al. Should exercises be painful in the management of chronic musculoskeletal pain? A systematic review and meta-analysis. Br J Sports Med. 2017;51:1679-1687. https://doi.org/10.1136/bjsports-2016-097383
- **18.** Sprague AL, Smith AH, Knox P, Pohlig RT, Silbernagel KG. Modifiable risk factors for patellar tendinopathy in athletes: a systematic review and meta-analysis. *Br J Sports Med*. 2018;52:1575-1585. https://doi.org/10.1136/bjsports-2017-099000
- Thomopoulos S, Birman V, Genin GM. Structural Interfaces and Attachments in Biology. New York, NY: Springer; 2012.
- 20. Thorpe CT, Riley GP, Birch HL, Clegg PD, Screen HRC. Fascicles and the interfascicular matrix show adaptation for fatigue resistance in energy storing tendons. *Acta Biomater*. 2016;42:308-315. https://doi.org/10.1016/j.actbio.2016.06.012
- 21. Van der Worp H, de Poel HJ, Diercks RL, van den Akker-Scheek I, Zwerver J. Jumper's knee or lander's knee? A systematic review of the relation between jump biomechanics and patellar tendinopathy. *Int J Sports Med*. 2014;35:714-722. https://doi.org/10.1055/s-0033-1358674
- 22. Visnes H, Tegnander A, Bahr R. Ultrasound characteristics of the patellar and quadriceps tendons among young elite athletes. Scand J Med Sci Sports. 2015;25:205-215. https://doi. org/10.1111/sms.12191
- Wilson NA, Sheehan FT. Dynamic in vivo quadriceps lines-of-action. J Biomech. 2010;43:2106-2113. https://doi.org/10.1016/j. jbiomech.2010.04.002
- 24. Zeiss J, Saddemi SR, Ebraheim NA. MR imaging of the quadriceps tendon: normal layered configuration and its importance in cases of tendon rupture. AJR Am J Roentgenol. 1992;159:1031-1034. https://doi.org/10.2214/air.159.5.1414770
- 25. Zhang ZJ, Ng GY, Lee WC, Fu SN. Changes in morphological and elastic properties of patellar tendon in athletes with unilateral patellar tendinopathy and their relationships with pain and functional disability. PLoS One. 2014;9:e108337. https://doi.org/10.1371/journal.pone.0108337

