

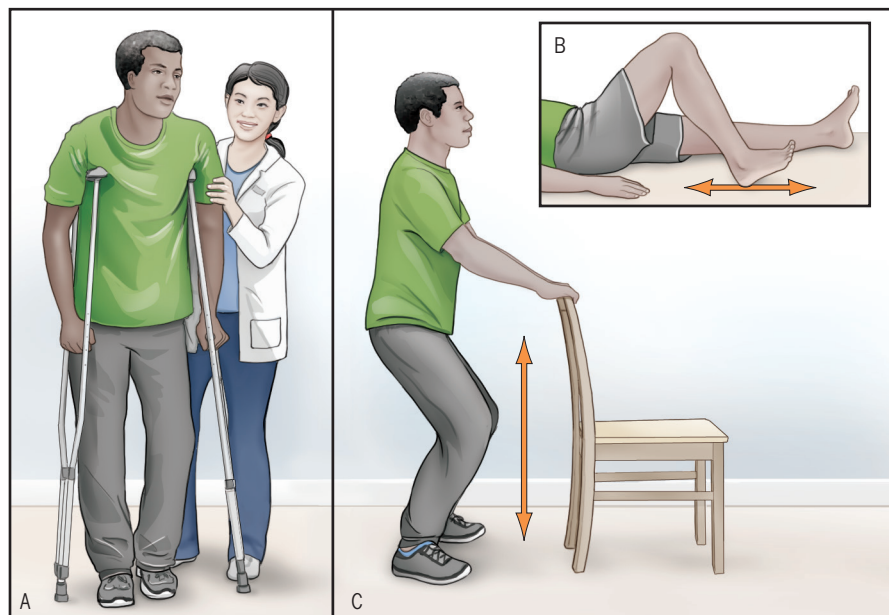
# Optimizing Recovery After Knee Meniscal or Cartilage Injury

## *Guidelines Help Deliver Quality Care*

*J Orthop Sports Phys Ther* 2018;48(2):125. doi:10.2519/jospt.2018.0504

**A**n injury to your knee meniscus or joint cartilage can happen when you move suddenly or repeatedly move the wrong way. If you have such an injury, you may feel knee pain and have limited motion. Physical therapists can ensure that you and others with these injuries receive quality care to optimize recovery. The goal of revised clinical practice guidelines published in the February 2018 issue of the *JOSPT* is to make recommenda-

tions based on best practices from recent published literature for the evaluation, diagnosis, treatment, and determination of patient readiness to return to activities following knee meniscus or joint cartilage injury. Based on scientific research, these guidelines summarize the treatment options currently available. Ultimately, the best care is a combination of the leading science, the clinical expertise of your health care provider, and your input as the patient.



**CRUTCHES AND EXERCISE.** If you have a meniscal or cartilage injury to your knee and need surgery, your recovery will often require crutches or a similar tool to help you walk. Crutches will allow you to walk while permitting the injury or surgical site to heal (A). Your physical therapist will talk with you about how much pressure to place on your leg while on crutches. You will also start exercises to help improve your knee's mobility and strength (B and C).

This *JOSPT Perspectives for Patients* is based on an article by Logerstedt et al, titled "Knee Pain and Mobility Impairments: Meniscal and Articular Cartilage Lesions Revision 2018" (*J Orthop Sports Phys Ther* 2018;48:A1-A50. doi:10.2519/jospt.2018.0301).

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

### NEW INSIGHTS

Expert clinicians and researchers reviewed research published from 2008 to 2016 to update the guidelines, which were first published in 2010. The authors screened 7692 articles and closely examined 88 of the best ones on this topic. They focused on finding the best existing evidence for diagnosis/classification, differential diagnosis, examination, and treatment options to decrease pain, improve mobility and function, and return you to activities after surgery for a knee meniscal or articular cartilage injury.

### PRACTICAL ADVICE

Protected weight bearing, early movement, and supervised rehabilitation—including therapeutic exercise and neuromuscular stimulation—offer the strongest evidence for patient improvement. Your recovery should include in-clinic treatment and exercises at home. You will use crutches to allow you to walk while enabling the injury or surgical site to heal. You may need crutches for up to 8 weeks.

Early in your recovery, you will be guided to improve your range of motion to reduce joint pain and fully straighten your knee. Ice may help decrease swelling and pain. Exercises to increase knee and hip muscle strength will be added over time.

The evidence suggests that neuromuscular stimulation may also help improve strength and function. These exercises improve coordination, confidence in movement, stability, power, and function to help you return to activities and sport. A conversation between you and your therapist and surgeon will determine how soon you may return to full activity.



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ON BEHALF OF THE MOA TRIAL TEAM

# The ShortMAC: Minimum Important Change of a Reduced Version of the Western Ontario and McMaster Universities Osteoarthritis Index

**P**erceived respondent burden, data completeness, and response rate are important considerations when designing outcome measure instruments for research and selecting appropriate questionnaires for use in clinical practice. Respondent burden

may be reduced by reducing questionnaire length (and therefore the time required to complete the questionnaire) through avoiding redundancies;

ensuring the questions are relevant to the patient's condition, sex, and culture; and keeping instructions clear and concise.<sup>20,25,29</sup>

The most widely accepted condition-specific patient-reported outcome instrument for assessing pain and physical function in people with osteoarthritis (OA) of the lower limbs is the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).<sup>6,8</sup> The WOMAC consists of 24 questions that measure pain (5 items), stiffness (2 items), and function (17 items) (TABLE 1). Whitehouse et al<sup>29</sup> recognized the necessity and benefits of shortening the WOMAC<sup>10,22</sup> and proposed an abridged version of the WOMAC. The resulting reduced WOMAC kept the WOMAC pain subscale (WOMAC-P) unchanged, eliminated the 2-item WOMAC stiffness subscale, and removed 10 items from the WOMAC physical function subscale (WOMAC-F) that were found to be differentially applicable to sex or cultural groups, redundant in the same construct (eg, eliminating 1 of 2 stair items), open to misinterpretation, a poor model fit, or associated with a high proportion of missing responses (TABLE 1).<sup>10,22</sup> Whitehouse et al<sup>29</sup> demonstrated the reliability, validity, and responsiveness (in terms of standardized response means) of the reduced WOMAC-F in a clinical cohort of patients with hip or knee OA undergoing total joint replacement surgery. Subsequently, Yang and

• **STUDY DESIGN:** Clinical measurement study; secondary analysis of randomized clinical trial data.

• **BACKGROUND:** A 12-item shortened version (ShortMAC) of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a condition-specific, patient-reported osteoarthritis index, has been derived, published, and validated. The minimum important change (MIC) of the ShortMAC has not been reported or compared with the traditional 24-item WOMAC.

• **OBJECTIVES:** To investigate the MIC of the 12-item ShortMAC and the traditional 24-item WOMAC across 3 levels of patient-perceived global change.

• **METHODS:** The Management of OsteoArthritis Trial cohort of 206 consecutive patients with knee or hip osteoarthritis was assessed at the initial visit and after 9 weeks of physical therapy (n = 155) or usual medical care (n = 51). The global rating of change instrument, assessed at the 9-week visit, provided the anchor. The MIC was calculated using

receiver operating characteristic curve methodology for the ShortMAC and the traditional WOMAC, across 3 levels of patient-perceived change (small, medium, and large change) defined by the global rating of change.

• **RESULTS:** The MICs for the ShortMAC and traditional WOMAC (both transformed to a scale from 0 to 100) were 7.9 and 9.8 points for small change, 8.4 and 9.8 points for medium change, and 12.1 and 10.1 points for large change, respectively. The MICs of the pain and function subscales are also reported for small, medium, and large changes.

• **CONCLUSION:** The lower point estimates for the MIC of the ShortMAC compared with that of the traditional WOMAC, using conventional definitions of MIC and half the number of items, indicate greater efficiency for use in clinical trials and reduced patient burden. *J Orthop Sports Phys Ther* 2018;48(2):81-86. Epub 21 Oct 2017. doi:10.2519/jospt.2018.7676

• **KEY WORDS:** minimum clinically important difference, minimum important difference, osteoarthritis, responsiveness

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colleagues<sup>32</sup> validated the internal consistency, reliability, and responsiveness of the reduced WOMAC-F in a nonsurgical cohort, thus showing its generalizability beyond patients undergoing total joint replacement, and recommended its use during nonsurgical interventions.

In clinical practice and research, it is crucial to be able to interpret the meaningfulness of change in the score of an outcome measure over time.<sup>15</sup> The most important clinimetric property for interpreting responsiveness to change is the minimum important change (MIC). The MIC of the shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index (ShortMAC) or its subscales has not been reported. The aim of this study was, therefore, to investigate the MIC of the ShortMAC (7-item reduced WOMAC-F plus 5-item WOMAC-P: a 12-item questionnaire) alongside the full, traditional version (24-item questionnaire) across 3 levels of patient-perceived importance.

## METHODS

**A** TOTAL OF 206 PATIENTS FROM THE Management of OsteoArthritis (MOA) Trial, a randomized controlled trial of nonsurgical interventions in patients with hip or knee OA, were evaluated at recruitment and again after 9 weeks of physical therapy interventions (n = 155) or usual medical care (n = 51).<sup>1</sup> Participating patients were referred to the trial by their general practitioner, or referred by their general practitioner to the Department of Orthopaedic Surgery (Outpatient Clinic, Dunedin Public Hospital, New Zealand) for an orthopaedic outpatient consultation, but did not meet the priority criteria to be wait-listed for hip or knee joint replacement surgery. Inclusion in this study required participants to meet the clinical criteria of knee or hip OA diagnosis as outlined by the American College of Rheumatology.<sup>3,4</sup> People with previous surgical intervention, recent analgesic initiation, and physical or mental impairment that

| <div>TABLE 1</div> <div>ITEMS INCLUDED IN THE TRADITIONAL WOMAC AND SHORTMAC INSTRUMENTS</div>                                                                                                                                                      |                   |          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------|
| Dimension Assessed/Item                                                                                                                                                                                                                             | Traditional WOMAC | ShortMAC |
| Pain                                                                                                                                                                                                                                                |                   |          |
| 1. While walking on a flat surface                                                                                                                                                                                                                  | X                 | X        |
| 2. Ascending or descending stairs                                                                                                                                                                                                                   | X                 | X        |
| 3. At night while in bed                                                                                                                                                                                                                            | X                 | X        |
| 4. Sitting or lying                                                                                                                                                                                                                                 | X                 | X        |
| 5. Standing upright                                                                                                                                                                                                                                 | X                 | X        |
| Stiffness                                                                                                                                                                                                                                           |                   |          |
| 1. On first waking in the morning                                                                                                                                                                                                                   | X                 |          |
| 2. Later in the day                                                                                                                                                                                                                                 | X                 |          |
| Function                                                                                                                                                                                                                                            |                   |          |
| 1. Descending stairs                                                                                                                                                                                                                                | X                 |          |
| 2. Ascending stairs                                                                                                                                                                                                                                 | X                 | X        |
| 3. Rising from sitting                                                                                                                                                                                                                              | X                 | X        |
| 4. Standing                                                                                                                                                                                                                                         | X                 |          |
| 5. Bending to floor                                                                                                                                                                                                                                 | X                 |          |
| 6. Walking on flat surface                                                                                                                                                                                                                          | X                 | X        |
| 7. Getting in/out of car                                                                                                                                                                                                                            | X                 | X        |
| 8. Going shopping                                                                                                                                                                                                                                   | X                 |          |
| 9. Putting on socks                                                                                                                                                                                                                                 | X                 | X        |
| 10. Rising from bed                                                                                                                                                                                                                                 | X                 | X        |
| 11. Taking off socks                                                                                                                                                                                                                                | X                 |          |
| 12. Lying in bed                                                                                                                                                                                                                                    | X                 |          |
| 13. Getting in/out of bed                                                                                                                                                                                                                           | X                 |          |
| 14. Sitting                                                                                                                                                                                                                                         | X                 | X        |
| 15. Getting on/off the toilet                                                                                                                                                                                                                       | X                 |          |
| 16. Heavy domestic duties                                                                                                                                                                                                                           | X                 |          |
| 17. Light domestic duties                                                                                                                                                                                                                           | X                 |          |
| Total number of items                                                                                                                                                                                                                               | 24                | 12       |
| Instrument range*                                                                                                                                                                                                                                   | 0-240             | 0-120    |
| Abbreviations: ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.<br>*A higher score indicates greater symptoms/limitations. |                   |          |

would prevent participation were excluded, as previously described.<sup>1</sup>

All of the participants completed questionnaires, including the traditional 24-item WOMAC (0-240 scale), at their initial assessment and again after 9 weeks of therapy or usual care. To aid in comparisons across studies, we report WOMAC scores both on the original scale and normalized to a 0-to-100 scale. At the 9-week assessment, participants also completed the 15-point global rating of functional change (GROC) instrument.<sup>16</sup> Global change instruments are

the recommended reference anchor for MIC studies.<sup>2,16,27</sup>

Three levels of change on the external anchor, the GROC instrument, were defined, as previously described.<sup>2</sup> These levels represented small, medium, or large patient-perceived change. The MICs were calculated for the traditional WOMAC and the ShortMAC, as well as for subscales (the WOMAC-P, the full WOMAC-F, and the reduced WOMAC-F), across the 3 levels of change, using receiver operating characteristic curve methodology,<sup>11</sup> and cross-checked with the sum-of-squares method

using the Youden approach, wherein sensitivity and specificity are equally weighted.<sup>13,14</sup> Using the GROC as the reference standard for change,<sup>11</sup> responsiveness was assessed first by using the area under the curve (AUC) to assess the ability of the scale to differentiate those patients who improved from those who did not<sup>11</sup> and, second, by assessing correlation with the GROC.<sup>11</sup> An AUC above 0.70<sup>11</sup> and a correlation of 0.50 or greater were considered acceptable responsiveness,<sup>11</sup> and a difference of 0.10 was considered significant.<sup>11</sup> Standard error of measurement (SEM) was calculated, and minimum detectable change (MDC) was defined at the 90% confidence level (MDC<sub>90</sub>) as  $SD_{\text{change}} \times 1.645$ , where  $SD_{\text{change}}$  is change in score in the group defined as no change (ie, GROC scores of 6 to 10) and 1.645 is the z-score for 2-sided 90% confidence limits.<sup>11</sup> In addition, internal consistency was assessed through calculation of Cronbach's alpha. We considered a coefficient over .7 acceptable and hypothesized reduced Cronbach's alpha in the ShortMAC, toward a desired upper limit of .95,<sup>26</sup> as evidence of reduced redundancy among instrument items.<sup>27,29,32</sup> The floor and ceiling effects were also investigated, where a maximum of 15% of participants reporting the worst or best possible score, respectively, across the instrument of interest was deemed acceptable.<sup>17</sup> Calculations were performed using IBM SPSS Statistics Version 24.0 (IBM Corporation, Armonk, NY).

## RESULTS

**T**HE BASELINE CHARACTERISTICS OF the 206 recruited participants are presented in **TABLE 2**, along with the self-reported scores from the 24-item WOMAC questionnaire and the 12-item reduced form at the initial and 9-week visits, the Cronbach alpha for each time point, numbers at each analysis level of the GROC, and correlations with the GROC at 9-week follow-up.

**TABLE 3** reports the SEM, MDC<sub>90</sub>, MIC, and AUC results. The point estimate of the MIC for the ShortMAC was lower

**TABLE 2**

### CHARACTERISTICS OF PARTICIPANTS AND DESCRIPTION OF DATA AT INITIAL AND FINAL VISITS\*

|                             | Baseline               | At 9 Weeks            |
|-----------------------------|------------------------|-----------------------|
| Age (n = 206), y            | 66.6 ± 9.5             |                       |
| Sex, n (%)                  |                        |                       |
| Male                        | 92 (44.7)              |                       |
| Female                      | 114 (55.3)             |                       |
| Traditional WOMAC (0-240)   | 101.00 ± 54.21 (2-223) | 82.53 ± 54.30 (2-206) |
| Cronbach alpha <sup>†</sup> | .974                   | .977                  |
| ShortMAC (0-120)            | 50.02 ± 27.54 (1-110)  | 40.51 ± 27.31 (0-108) |
| Cronbach alpha <sup>†</sup> | .954                   | .955                  |
| GROC (1-15)                 | NA                     |                       |
| Large change (13+)          | ...                    | 50                    |
| Medium change (12+)         | ...                    | 66                    |
| Small change (11+)          | ...                    | 87                    |
| No change (6-10)            | ...                    | 86                    |
| Worse (1-5)                 | ...                    | 33                    |
| Correlations with GROC      | NA                     |                       |
| Traditional WOMAC           | ...                    | 0.59 <sup>‡</sup>     |
| ShortMAC                    | ...                    | 0.57 <sup>‡</sup>     |
| WOMAC-P subscale            | ...                    | 0.53 <sup>‡</sup>     |
| Traditional WOMAC-F         | ...                    | 0.57 <sup>‡</sup>     |
| ShortMAC-F subscale         | ...                    | 0.55 <sup>‡</sup>     |

Abbreviations: F, function; GROC, global rating of change; NA, not applicable; P, pain; ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.  
\*Values are mean ± SD or mean ± SD (range) unless otherwise indicated.  
<sup>†</sup>Cronbach alpha is an indicator of internal consistency.  
<sup>‡</sup>P < .001.

than that for the traditional WOMAC at small and medium, but not large, levels of change; however, responsiveness did not significantly differ by AUC or correlation (**TABLES 2 and 3**). The lower bound of the 95% confidence interval of the AUC exceeded 0.70 for all scales and subscales at each level investigated. **TABLE 4** reports the proportion of minimum score (floor) or maximum score (ceiling) totals reported for the full WOMAC and ShortMAC. There was no evidence of significant floor or ceiling effects at either time point across the instruments, or at total scale or subscale levels.

## DISCUSSION

**W**ITH THE INCREASED PROMINENCE of patient-reported outcomes in clinical practice and research,

interpreting the meaning of outcome measure change is essential. To our knowledge, this is the first study to report the MIC for both the traditional WOMAC and a reduced-item form of the WOMAC instrument. Within this same sample of patients with a wide spectrum of hip or knee OA, receiving physical therapy interventions or usual medical care, we have shown that the ShortMAC was similarly responsive to change. While the ShortMAC has a lower point estimate for the MIC compared with that of the traditional WOMAC at the small and medium levels, responsiveness was not significantly different in any analysis. The ShortMAC's fewer number of items and slightly lower MIC have favorable implications both for the efficiency of questionnaire administration and for the efficiency of sample-size requirements for clinical trials.

# [ BRIEF REPORT ]

TABLE 3

## MIC AND AUC FOR THE TRADITIONAL AND REDUCED WOMAC INSTRUMENTS AND SUBSCALES

| Outcome Measure            | No Change<br>(n = 86) | Small Change (GROC 11+) (n = 87)* |                  |                      | Medium Change (GROC 12+) (n = 66)* |                  |                      | Large Change (GROC 13+) (n = 50)* |                  |                      |
|----------------------------|-----------------------|-----------------------------------|------------------|----------------------|------------------------------------|------------------|----------------------|-----------------------------------|------------------|----------------------|
|                            |                       | MIC <sup>†</sup>                  | MIC <sup>‡</sup> | AUC <sup>§</sup>     | MIC <sup>†</sup>                   | MIC <sup>‡</sup> | AUC <sup>§</sup>     | MIC <sup>†</sup>                  | MIC <sup>‡</sup> | AUC <sup>§</sup>     |
| Traditional WOMAC (0-240)  |                       | 23.5                              | 9.8              | 0.802 (0.738, 0.865) | 23.5                               | 9.8              | 0.822 (0.756, 0.888) | 24.125                            | 10.1             | 0.838 (0.774, 0.901) |
| SEM                        | 7.6                   |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| SDC <sub>90</sub>          | 17.7                  |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| ShortMAC (0-120)           |                       | 9.5                               | 7.9              | 0.788 (0.724, 0.851) | 10.125                             | 8.4              | 0.819 (0.754, 0.885) | 14.5                              | 12.1             | 0.835 (0.769, 0.902) |
| SEM                        | 7.6                   |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| SDC <sub>90</sub>          | 17.7                  |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| WOMAC-P subscale (0-50)    |                       | 2.5                               | 5.0              | 0.779 (0.715, 0.843) | 4.5                                | 9.0              | 0.814 (0.751, 0.877) | 5.5                               | 11.0             | 0.808 (0.736, 0.880) |
| SEM                        | 9.7                   |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| SDC <sub>90</sub>          | 22.6                  |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| WOMAC-F subscale (0-170)   |                       | 5.5                               | 3.2              | 0.798 (0.732, 0.863) | 5.5                                | 3.2              | 0.826 (0.759, 0.894) | 5.5                               | 3.2              | 0.840 (0.776, 0.903) |
| SEM                        | 8.0                   |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| SDC <sub>90</sub>          | 18.6                  |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| ShortMAC-F subscale (0-70) |                       | 6.5                               | 9.3              | 0.774 (0.708, 0.841) | 5.5                                | 7.9              | 0.806 (0.736, 0.877) | 8.5                               | 12.1             | 0.831 (0.764, 0.899) |
| SEM                        | 7.6                   |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| SDC <sub>90</sub>          | 17.7                  |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |

Abbreviations: AUC, area under the receiver operating characteristic curve; F, function; GROC, global rating of change; MIC, minimum important change; P, pain; SDC<sub>90</sub>, smallest detectable change at upper bound of 90% confidence limits; SEM, standard error of measurement; ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

\*Small, greater than or equal to "somewhat better" on the GROC; medium, greater than or equal to "moderately better" on the GROC; large, greater than or equal to "quite a bit better" on the GROC, as rated by participants.

<sup>†</sup>Original scale.

<sup>‡</sup>Transformed scale (0-100).

<sup>§</sup>Values in parentheses are 95% confidence interval.

TABLE 4

## FLOOR AND CEILING EFFECTS OF THE TRADITIONAL AND REDUCED WOMAC INSTRUMENTS AND SUBSCALES

| Outcome Measure            | Relevant Measure            | Baseline                        |                                  | 9 Weeks                         |                                  |
|----------------------------|-----------------------------|---------------------------------|----------------------------------|---------------------------------|----------------------------------|
|                            |                             | Floor Effect<br>(Worst Outcome) | Ceiling Effect<br>(Best Outcome) | Floor Effect<br>(Worst Outcome) | Ceiling Effect<br>(Best Outcome) |
| Traditional WOMAC (0-240)  | Traditional WOMAC           | 0%                              | 0%                               | 0%                              | 0%                               |
| ShortMAC (0-120)           | ShortMAC                    | 0%                              | 0%                               | 0%                              | 1/206, 0.5%                      |
| Subscales                  |                             |                                 |                                  |                                 |                                  |
| WOMAC-P subscale (0-50)    | Traditional WOMAC, ShortMAC | 0%                              | 2/206, 1%                        | 0%                              | 6/206, 2.9%                      |
| WOMAC-S subscale (0-20)    | Traditional WOMAC           | 1/206, 0.5%                     | 8/206, 3.9%                      | 1/206, 0.5%                     | 11/206, 5.3%                     |
| WOMAC-F subscale (0-170)   | Traditional WOMAC           | 0%                              | 2/206, 1%                        | 0%                              | 1/206, 0.5%                      |
| ShortMAC-F subscale (0-70) | ShortMAC                    | 0%                              | 4/206, 1.9%                      | 0%                              | 4/206, 1.9%                      |

Abbreviations: F, function; P, pain; S, stiffness; ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

The baseline WOMAC values and the extent of change are consistent with those reported previously in studies looking at nonsurgical treatment of OA of the lower extremity,<sup>5,30,32</sup> supporting the external

validity of our MIC estimates. Williams et al<sup>30</sup> reported the MIC for the WOMAC at 2 months to be 4.0 (0-100 scale) using the Youden index to identify the MIC estimate (sensitivity and specificity equally weight-

ed), or 8.8 when using a specificity value of 0.80. Those MIC values, and those found in the current study, are lower than the 14 to 22 points reported by Escobar et al<sup>12</sup> (0-100 scale) in individuals undergoing

total joint replacement and, therefore, in whom larger changes would be expected. They also used a different anchor question with larger steps.

The MICs corresponding to small, medium, and large self-perceived changes were remarkably stable for both instruments. The ShortMAC demonstrated appropriate stepwise increases in the MIC for increasing levels of the GROC, which were less evident for the full WOMAC version. This is likely due to reduced item redundancy and can be interpreted as evidence of greater sensitivity to change of the ShortMAC. Because we used a 15-point scale in the GROC, the numbers of respondents per scale point were relatively small (eg, only 12 of 206 participants reported feeling “moderately better”); however, categorizing the GROC responses into 3 levels of change ensured sufficient numbers at each level (TABLE 2), giving us the ability to show the extent of MIC improvement across levels of patient-perceived change.

One of the limitations of this research that must be considered is the anchor used in the present study, the GROC instrument, which asked participants to compare the current impact of OA on their overall health status to its impact 9 weeks earlier and at baseline. Although the GROC has been shown to reflect a bias toward current status rather than equally weighting both current and baseline components of “change,”<sup>18,23,24</sup> it is still the recommended reference anchor for MIC studies.<sup>2,11,16,27</sup> Also, it captures more domains of health status than merely pain and physical function, so it does not correlate exactly with the WOMAC. Also, as with any self-reported questionnaire, the GROC is limited by the accuracy of patients’ recall, so it is not recommended for use in clinical practice or for other applications with differing periods of recall.<sup>23,24</sup> In this study, the recall time was consistent between the 2 instruments, and a 9-week recall period is short enough to not be considered problematic.<sup>26</sup> The MIC estimates were lower than the MDC<sub>90</sub>, limiting the interpreta-

tion of the MIC for individual patients.<sup>11</sup> However, the test-retest scores used to calculate the SEM and MDC<sub>90</sub> were conducted 9 weeks apart and, while ideal for estimating the MIC, were likely to bias MDC upward. Other sources recommend SEM or  $0.5 \times SD_{\text{change}}$  as another way to estimate real change over measurement variability, the latter of which, in this case, would be 5.4 to 6.9 points.<sup>11,15</sup> Finding the true MDC would require further research specifically assessing test-retest reliability of the instruments in unchanged participants.

As noted previously,<sup>29,32</sup> Cronbach’s alpha was particularly high in the traditional WOMAC, highlighting the apparent redundancy present in the instrument. Reducing the questionnaire decreased this value toward the desired upper limit of .95,<sup>26</sup> thereby producing more favorable internal consistency, but to a lesser extent than had been previously reported.<sup>29,32</sup> A ceiling effect in the traditional WOMAC has been reported following surgical intervention.<sup>9,12,19,21</sup> In the current study, where nonsurgical intervention was applied, the traditional and reduced-form WOMAC instruments and subscales demonstrated an absence of any floor effects, and minimal ceiling effects well within acceptable levels. This is consistent with earlier research, Yang et al<sup>32</sup> also having reported minimal overall floor and ceiling effects after “conservative” treatment.

The patients included in the current study were involved in a trial of nonoperative therapy for OA of the lower limb. While the type of therapy and its efficacy are of little relevance to the objectives of the current study, at the time of recruitment, these participants were deemed to have a wide spectrum of symptom severity, from mild to significantly impaired by OA, but were not on the waiting list for total joint replacement surgery. As such, their disease burden would be expected to cover a broader range but average less than that of patients referred for surgery, and their treatment effects to be less marked than those in patients scheduled for total joint replacement. Both the traditional WOM-

AC and the ShortMAC have the sensitivity to detect change with nonoperative therapy, thereby expanding their applicability beyond surgical intervention studies.<sup>29,32</sup>

Also with regard to generalizability, to aid in comparisons across studies, we reported both the raw scores and results normalized to a 0-to-100 scale. The traditional WOMAC instrument is available in 3 formats: 5-point Likert scale (range, 0-96), 100-mm visual analog scale (range, 0-240), and, as in the current study, 11-point numeric rating scale (range, 0-240).<sup>7</sup> While no systematic differences have been reported between the scales, given these modifications and others adopted in the literature, it is essential that the scale and the score range be clearly defined.<sup>31</sup>

Other studies have proposed short-form versions of the WOMAC, including reducing the number of items in the WOMAC-P subscale, but no consensus has been reached.<sup>10,22,28</sup> This ShortMAC, a reduced version of the WOMAC, is the only reduced version to have been independently tested in both surgical and nonsurgical patient populations, and for which MIC estimates are available.<sup>29,32</sup>

## CONCLUSION

THE RESULTS OF THIS STUDY SUPPORT recommendation of the reduced-form WOMAC as a patient-friendly alternative to the traditional WOMAC instrument to assess the impact of OA on a patient’s daily life, and as a valid and responsive means of assessing change in status following surgical or nonsurgical intervention. ●

**ACKNOWLEDGMENTS:** *Many thanks to the MOA Trial field team (APPENDIX, available at [www.jospt.org](http://www.jospt.org)) and participants.*

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## APPENDIX

### THE MOA TRIAL TEAM

| Name                                             | Role on Trial Team                             | Contribution                                                                                 | Affiliation                              |
|--------------------------------------------------|------------------------------------------------|----------------------------------------------------------------------------------------------|------------------------------------------|
| Professor J. Haxby Abbott                        | Principal investigator                         | Conception, design, protocols, coordination, monitoring, analysis, interpretation, reporting | University of Otago                      |
| Professor A. John Campbell (deceased)            | Coinvestigator, consultant geriatrician        | Design, coordination, interpretation                                                         | University of Otago                      |
| Associate Professor M. Clare Robertson (retired) | Coinvestigator                                 | Economic evaluation, design, protocols, coordination, monitoring, interpretation             | University of Otago                      |
| Professor G. David Baxter                        | Coinvestigator                                 | Coordination, monitoring                                                                     | University of Otago                      |
| Professor Jean-Claude Theis                      | Coinvestigator, consultant orthopaedic surgeon | Coordination, monitoring, recruitment                                                        | University of Otago                      |
| Professor Paul Hansen                            | Health economist                               | Design and interpretation                                                                    | University of Otago                      |
| Dr Joanne E. McKenzie                            | Statistician                                   | Protocol design                                                                              | University of Otago<br>Monash University |
| Debra McNamara                                   | Research nurse                                 | Participant recruitment and screening                                                        | University of Otago                      |
| Dr Catherine Chapple                             | Outcome assessor                               | Design of intervention protocols                                                             | University of Otago                      |
| Dr Daniel Pinto                                  | Outcome assessor                               | Design of intervention protocols                                                             | University of Otago                      |
| Dr Alexis Wright                                 | Outcome assessor                               | Design of intervention protocols                                                             | University of Otago                      |
| Martin Kidd                                      | Physical therapist                             | Intervention protocol design and delivery                                                    | University of Otago                      |
| Chris Higgs                                      | Physical therapist                             | Intervention protocol design and delivery                                                    | University of Otago                      |
| Jessica Smith                                    | Physical therapist                             | Intervention protocol design and delivery                                                    | University of Otago                      |

Associate members: acknowledgment and thanks to the following for contributions:

| Name                           | Contribution                                                             | Affiliation                                   |
|--------------------------------|--------------------------------------------------------------------------|-----------------------------------------------|
| Professor Peter Herbison       | Statistical design advice                                                | University of Otago                           |
| Professor Jeffrey Basford      | Research advisor, design                                                 | Mayo Clinic                                   |
| Professor G. Kelley Fitzgerald | Research and clinical advisor, design, interventions                     | University of Pittsburgh                      |
| Professor Timothy Flynn        | Research and clinical advisor, design                                    | Regis University<br>Rocky Mountain University |
| Professor Julie Fritz          | Research advisor, design                                                 | University of Utah                            |
| Dr Deidre Hurley-Osing         | Research advisor, design                                                 | University College Dublin                     |
| Dr Julie Whitman               | Clinical advisor, design                                                 | Regis University                              |
| Dr Steve Tumilty               | Physical therapist, intervention delivery                                | University of Otago                           |
| Dr Ewan Kennedy                | Physical therapist, intervention delivery                                | University of Otago                           |
| Dr Rhiannon Braund             | Clinical pharmacist, health resource (medications) use assessment advice | University of Otago                           |

J. HAXBY ABBOTT, DPT, PhD, FNZCP<sup>1</sup> • CATHERINE HOBBS, PhD<sup>1</sup> • DAVID GWYNNE-JONES, MA, BM BCh, FRACS<sup>1</sup>  
ON BEHALF OF THE MOA TRIAL TEAM

# The ShortMAC: Minimum Important Change of a Reduced Version of the Western Ontario and McMaster Universities Osteoarthritis Index

**P**erceived respondent burden, data completeness, and response rate are important considerations when designing outcome measure instruments for research and selecting appropriate questionnaires for use in clinical practice. Respondent burden

may be reduced by reducing questionnaire length (and therefore the time required to complete the questionnaire) through avoiding redundancies;

ensuring the questions are relevant to the patient's condition, sex, and culture; and keeping instructions clear and concise.<sup>20,25,29</sup>

The most widely accepted condition-specific patient-reported outcome instrument for assessing pain and physical function in people with osteoarthritis (OA) of the lower limbs is the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC).<sup>6,8</sup> The WOMAC consists of 24 questions that measure pain (5 items), stiffness (2 items), and function (17 items) (TABLE 1). Whitehouse et al<sup>29</sup> recognized the necessity and benefits of shortening the WOMAC<sup>10,22</sup> and proposed an abridged version of the WOMAC. The resulting reduced WOMAC kept the WOMAC pain subscale (WOMAC-P) unchanged, eliminated the 2-item WOMAC stiffness subscale, and removed 10 items from the WOMAC physical function subscale (WOMAC-F) that were found to be differentially applicable to sex or cultural groups, redundant in the same construct (eg, eliminating 1 of 2 stair items), open to misinterpretation, a poor model fit, or associated with a high proportion of missing responses (TABLE 1).<sup>10,22</sup> Whitehouse et al<sup>29</sup> demonstrated the reliability, validity, and responsiveness (in terms of standardized response means) of the reduced WOMAC-F in a clinical cohort of patients with hip or knee OA undergoing total joint replacement surgery. Subsequently, Yang and

• **STUDY DESIGN:** Clinical measurement study; secondary analysis of randomized clinical trial data.

• **BACKGROUND:** A 12-item shortened version (ShortMAC) of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), a condition-specific, patient-reported osteoarthritis index, has been derived, published, and validated. The minimum important change (MIC) of the ShortMAC has not been reported or compared with the traditional 24-item WOMAC.

• **OBJECTIVES:** To investigate the MIC of the 12-item ShortMAC and the traditional 24-item WOMAC across 3 levels of patient-perceived global change.

• **METHODS:** The Management of OsteoArthritis Trial cohort of 206 consecutive patients with knee or hip osteoarthritis was assessed at the initial visit and after 9 weeks of physical therapy (n = 155) or usual medical care (n = 51). The global rating of change instrument, assessed at the 9-week visit, provided the anchor. The MIC was calculated using

receiver operating characteristic curve methodology for the ShortMAC and the traditional WOMAC, across 3 levels of patient-perceived change (small, medium, and large change) defined by the global rating of change.

• **RESULTS:** The MICs for the ShortMAC and traditional WOMAC (both transformed to a scale from 0 to 100) were 7.9 and 9.8 points for small change, 8.4 and 9.8 points for medium change, and 12.1 and 10.1 points for large change, respectively. The MICs of the pain and function subscales are also reported for small, medium, and large changes.

• **CONCLUSION:** The lower point estimates for the MIC of the ShortMAC compared with that of the traditional WOMAC, using conventional definitions of MIC and half the number of items, indicate greater efficiency for use in clinical trials and reduced patient burden. *J Orthop Sports Phys Ther* 2018;48(2):81-86. Epub 21 Oct 2017. doi:10.2519/jospt.2018.7676

• **KEY WORDS:** minimum clinically important difference, minimum important difference, osteoarthritis, responsiveness

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colleagues<sup>32</sup> validated the internal consistency, reliability, and responsiveness of the reduced WOMAC-F in a nonsurgical cohort, thus showing its generalizability beyond patients undergoing total joint replacement, and recommended its use during nonsurgical interventions.

In clinical practice and research, it is crucial to be able to interpret the meaningfulness of change in the score of an outcome measure over time.<sup>15</sup> The most important clinimetric property for interpreting responsiveness to change is the minimum important change (MIC). The MIC of the shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index (ShortMAC) or its subscales has not been reported. The aim of this study was, therefore, to investigate the MIC of the ShortMAC (7-item reduced WOMAC-F plus 5-item WOMAC-P: a 12-item questionnaire) alongside the full, traditional version (24-item questionnaire) across 3 levels of patient-perceived importance.

## METHODS

**A** TOTAL OF 206 PATIENTS FROM THE Management of OsteoArthritis (MOA) Trial, a randomized controlled trial of nonsurgical interventions in patients with hip or knee OA, were evaluated at recruitment and again after 9 weeks of physical therapy interventions (n = 155) or usual medical care (n = 51).<sup>1</sup> Participating patients were referred to the trial by their general practitioner, or referred by their general practitioner to the Department of Orthopaedic Surgery (Outpatient Clinic, Dunedin Public Hospital, New Zealand) for an orthopaedic outpatient consultation, but did not meet the priority criteria to be wait-listed for hip or knee joint replacement surgery. Inclusion in this study required participants to meet the clinical criteria of knee or hip OA diagnosis as outlined by the American College of Rheumatology.<sup>3,4</sup> People with previous surgical intervention, recent analgesic initiation, and physical or mental impairment that

| <div>TABLE 1</div> <div>ITEMS INCLUDED IN THE TRADITIONAL WOMAC AND SHORTMAC INSTRUMENTS</div>                                                                                                                                                      |                   |          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------|
| Dimension Assessed/Item                                                                                                                                                                                                                             | Traditional WOMAC | ShortMAC |
| Pain                                                                                                                                                                                                                                                |                   |          |
| 1. While walking on a flat surface                                                                                                                                                                                                                  | X                 | X        |
| 2. Ascending or descending stairs                                                                                                                                                                                                                   | X                 | X        |
| 3. At night while in bed                                                                                                                                                                                                                            | X                 | X        |
| 4. Sitting or lying                                                                                                                                                                                                                                 | X                 | X        |
| 5. Standing upright                                                                                                                                                                                                                                 | X                 | X        |
| Stiffness                                                                                                                                                                                                                                           |                   |          |
| 1. On first waking in the morning                                                                                                                                                                                                                   | X                 |          |
| 2. Later in the day                                                                                                                                                                                                                                 | X                 |          |
| Function                                                                                                                                                                                                                                            |                   |          |
| 1. Descending stairs                                                                                                                                                                                                                                | X                 |          |
| 2. Ascending stairs                                                                                                                                                                                                                                 | X                 | X        |
| 3. Rising from sitting                                                                                                                                                                                                                              | X                 | X        |
| 4. Standing                                                                                                                                                                                                                                         | X                 |          |
| 5. Bending to floor                                                                                                                                                                                                                                 | X                 |          |
| 6. Walking on flat surface                                                                                                                                                                                                                          | X                 | X        |
| 7. Getting in/out of car                                                                                                                                                                                                                            | X                 | X        |
| 8. Going shopping                                                                                                                                                                                                                                   | X                 |          |
| 9. Putting on socks                                                                                                                                                                                                                                 | X                 | X        |
| 10. Rising from bed                                                                                                                                                                                                                                 | X                 | X        |
| 11. Taking off socks                                                                                                                                                                                                                                | X                 |          |
| 12. Lying in bed                                                                                                                                                                                                                                    | X                 |          |
| 13. Getting in/out of bed                                                                                                                                                                                                                           | X                 |          |
| 14. Sitting                                                                                                                                                                                                                                         | X                 | X        |
| 15. Getting on/off the toilet                                                                                                                                                                                                                       | X                 |          |
| 16. Heavy domestic duties                                                                                                                                                                                                                           | X                 |          |
| 17. Light domestic duties                                                                                                                                                                                                                           | X                 |          |
| Total number of items                                                                                                                                                                                                                               | 24                | 12       |
| Instrument range*                                                                                                                                                                                                                                   | 0-240             | 0-120    |
| Abbreviations: ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.<br>*A higher score indicates greater symptoms/limitations. |                   |          |

would prevent participation were excluded, as previously described.<sup>1</sup>

All of the participants completed questionnaires, including the traditional 24-item WOMAC (0-240 scale), at their initial assessment and again after 9 weeks of therapy or usual care. To aid in comparisons across studies, we report WOMAC scores both on the original scale and normalized to a 0-to-100 scale. At the 9-week assessment, participants also completed the 15-point global rating of functional change (GROC) instrument.<sup>16</sup> Global change instruments are

the recommended reference anchor for MIC studies.<sup>2,16,27</sup>

Three levels of change on the external anchor, the GROC instrument, were defined, as previously described.<sup>2</sup> These levels represented small, medium, or large patient-perceived change. The MICs were calculated for the traditional WOMAC and the ShortMAC, as well as for subscales (the WOMAC-P, the full WOMAC-F, and the reduced WOMAC-F), across the 3 levels of change, using receiver operating characteristic curve methodology,<sup>11</sup> and cross-checked with the sum-of-squares method

using the Youden approach, wherein sensitivity and specificity are equally weighted.<sup>13,14</sup> Using the GROC as the reference standard for change,<sup>11</sup> responsiveness was assessed first by using the area under the curve (AUC) to assess the ability of the scale to differentiate those patients who improved from those who did not<sup>11</sup> and, second, by assessing correlation with the GROC.<sup>11</sup> An AUC above 0.70<sup>11</sup> and a correlation of 0.50 or greater were considered acceptable responsiveness,<sup>11</sup> and a difference of 0.10 was considered significant.<sup>11</sup> Standard error of measurement (SEM) was calculated, and minimum detectable change (MDC) was defined at the 90% confidence level (MDC<sub>90</sub>) as  $SD_{\text{change}} \times 1.645$ , where  $SD_{\text{change}}$  is change in score in the group defined as no change (ie, GROC scores of 6 to 10) and 1.645 is the z-score for 2-sided 90% confidence limits.<sup>11</sup> In addition, internal consistency was assessed through calculation of Cronbach's alpha. We considered a coefficient over .7 acceptable and hypothesized reduced Cronbach's alpha in the ShortMAC, toward a desired upper limit of .95,<sup>26</sup> as evidence of reduced redundancy among instrument items.<sup>27,29,32</sup> The floor and ceiling effects were also investigated, where a maximum of 15% of participants reporting the worst or best possible score, respectively, across the instrument of interest was deemed acceptable.<sup>17</sup> Calculations were performed using IBM SPSS Statistics Version 24.0 (IBM Corporation, Armonk, NY).

## RESULTS

**T**HE BASELINE CHARACTERISTICS OF the 206 recruited participants are presented in **TABLE 2**, along with the self-reported scores from the 24-item WOMAC questionnaire and the 12-item reduced form at the initial and 9-week visits, the Cronbach alpha for each time point, numbers at each analysis level of the GROC, and correlations with the GROC at 9-week follow-up.

**TABLE 3** reports the SEM, MDC<sub>90</sub>, MIC, and AUC results. The point estimate of the MIC for the ShortMAC was lower

**TABLE 2**

### CHARACTERISTICS OF PARTICIPANTS AND DESCRIPTION OF DATA AT INITIAL AND FINAL VISITS\*

|                             | Baseline               | At 9 Weeks            |
|-----------------------------|------------------------|-----------------------|
| Age (n = 206), y            | 66.6 ± 9.5             |                       |
| Sex, n (%)                  |                        |                       |
| Male                        | 92 (44.7)              |                       |
| Female                      | 114 (55.3)             |                       |
| Traditional WOMAC (0-240)   | 101.00 ± 54.21 (2-223) | 82.53 ± 54.30 (2-206) |
| Cronbach alpha <sup>†</sup> | .974                   | .977                  |
| ShortMAC (0-120)            | 50.02 ± 27.54 (1-110)  | 40.51 ± 27.31 (0-108) |
| Cronbach alpha <sup>†</sup> | .954                   | .955                  |
| GROC (1-15)                 | NA                     |                       |
| Large change (13+)          | ...                    | 50                    |
| Medium change (12+)         | ...                    | 66                    |
| Small change (11+)          | ...                    | 87                    |
| No change (6-10)            | ...                    | 86                    |
| Worse (1-5)                 | ...                    | 33                    |
| Correlations with GROC      | NA                     |                       |
| Traditional WOMAC           | ...                    | 0.59 <sup>‡</sup>     |
| ShortMAC                    | ...                    | 0.57 <sup>‡</sup>     |
| WOMAC-P subscale            | ...                    | 0.53 <sup>‡</sup>     |
| Traditional WOMAC-F         | ...                    | 0.57 <sup>‡</sup>     |
| ShortMAC-F subscale         | ...                    | 0.55 <sup>‡</sup>     |

*Abbreviations: F, function; GROC, global rating of change; NA, not applicable; P, pain; ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.*  
*\*Values are mean ± SD or mean ± SD (range) unless otherwise indicated.*  
<sup>†</sup>Cronbach alpha is an indicator of internal consistency.  
<sup>‡</sup>P < .001.

than that for the traditional WOMAC at small and medium, but not large, levels of change; however, responsiveness did not significantly differ by AUC or correlation (**TABLES 2 and 3**). The lower bound of the 95% confidence interval of the AUC exceeded 0.70 for all scales and subscales at each level investigated. **TABLE 4** reports the proportion of minimum score (floor) or maximum score (ceiling) totals reported for the full WOMAC and ShortMAC. There was no evidence of significant floor or ceiling effects at either time point across the instruments, or at total scale or subscale levels.

## DISCUSSION

**W**ITH THE INCREASED PROMINENCE of patient-reported outcomes in clinical practice and research,

interpreting the meaning of outcome measure change is essential. To our knowledge, this is the first study to report the MIC for both the traditional WOMAC and a reduced-item form of the WOMAC instrument. Within this same sample of patients with a wide spectrum of hip or knee OA, receiving physical therapy interventions or usual medical care, we have shown that the ShortMAC was similarly responsive to change. While the ShortMAC has a lower point estimate for the MIC compared with that of the traditional WOMAC at the small and medium levels, responsiveness was not significantly different in any analysis. The ShortMAC's fewer number of items and slightly lower MIC have favorable implications both for the efficiency of questionnaire administration and for the efficiency of sample-size requirements for clinical trials.

# [ BRIEF REPORT ]

TABLE 3

## MIC AND AUC FOR THE TRADITIONAL AND REDUCED WOMAC INSTRUMENTS AND SUBSCALES

| Outcome Measure            | No Change<br>(n = 86) | Small Change (GROC 11+) (n = 87)* |                  |                      | Medium Change (GROC 12+) (n = 66)* |                  |                      | Large Change (GROC 13+) (n = 50)* |                  |                      |
|----------------------------|-----------------------|-----------------------------------|------------------|----------------------|------------------------------------|------------------|----------------------|-----------------------------------|------------------|----------------------|
|                            |                       | MIC <sup>†</sup>                  | MIC <sup>‡</sup> | AUC <sup>§</sup>     | MIC <sup>†</sup>                   | MIC <sup>‡</sup> | AUC <sup>§</sup>     | MIC <sup>†</sup>                  | MIC <sup>‡</sup> | AUC <sup>§</sup>     |
| Traditional WOMAC (0-240)  |                       | 23.5                              | 9.8              | 0.802 (0.738, 0.865) | 23.5                               | 9.8              | 0.822 (0.756, 0.888) | 24.125                            | 10.1             | 0.838 (0.774, 0.901) |
| SEM                        | 7.6                   |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| SDC <sub>90</sub>          | 17.7                  |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| ShortMAC (0-120)           |                       | 9.5                               | 7.9              | 0.788 (0.724, 0.851) | 10.125                             | 8.4              | 0.819 (0.754, 0.885) | 14.5                              | 12.1             | 0.835 (0.769, 0.902) |
| SEM                        | 7.6                   |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| SDC <sub>90</sub>          | 17.7                  |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| WOMAC-P subscale (0-50)    |                       | 2.5                               | 5.0              | 0.779 (0.715, 0.843) | 4.5                                | 9.0              | 0.814 (0.751, 0.877) | 5.5                               | 11.0             | 0.808 (0.736, 0.880) |
| SEM                        | 9.7                   |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| SDC <sub>90</sub>          | 22.6                  |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| WOMAC-F subscale (0-170)   |                       | 5.5                               | 3.2              | 0.798 (0.732, 0.863) | 5.5                                | 3.2              | 0.826 (0.759, 0.894) | 5.5                               | 3.2              | 0.840 (0.776, 0.903) |
| SEM                        | 8.0                   |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| SDC <sub>90</sub>          | 18.6                  |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| ShortMAC-F subscale (0-70) |                       | 6.5                               | 9.3              | 0.774 (0.708, 0.841) | 5.5                                | 7.9              | 0.806 (0.736, 0.877) | 8.5                               | 12.1             | 0.831 (0.764, 0.899) |
| SEM                        | 7.6                   |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |
| SDC <sub>90</sub>          | 17.7                  |                                   |                  |                      |                                    |                  |                      |                                   |                  |                      |

Abbreviations: AUC, area under the receiver operating characteristic curve; F, function; GROC, global rating of change; MIC, minimum important change; P, pain; SDC<sub>90</sub>, smallest detectable change at upper bound of 90% confidence limits; SEM, standard error of measurement; ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

\*Small, greater than or equal to "somewhat better" on the GROC; medium, greater than or equal to "moderately better" on the GROC; large, greater than or equal to "quite a bit better" on the GROC, as rated by participants.

<sup>†</sup>Original scale.

<sup>‡</sup>Transformed scale (0-100).

<sup>§</sup>Values in parentheses are 95% confidence interval.

TABLE 4

## FLOOR AND CEILING EFFECTS OF THE TRADITIONAL AND REDUCED WOMAC INSTRUMENTS AND SUBSCALES

| Outcome Measure            | Relevant Measure            | Baseline                        |                                  | 9 Weeks                         |                                  |
|----------------------------|-----------------------------|---------------------------------|----------------------------------|---------------------------------|----------------------------------|
|                            |                             | Floor Effect<br>(Worst Outcome) | Ceiling Effect<br>(Best Outcome) | Floor Effect<br>(Worst Outcome) | Ceiling Effect<br>(Best Outcome) |
| Traditional WOMAC (0-240)  | Traditional WOMAC           | 0%                              | 0%                               | 0%                              | 0%                               |
| ShortMAC (0-120)           | ShortMAC                    | 0%                              | 0%                               | 0%                              | 1/206, 0.5%                      |
| Subscales                  |                             |                                 |                                  |                                 |                                  |
| WOMAC-P subscale (0-50)    | Traditional WOMAC, ShortMAC | 0%                              | 2/206, 1%                        | 0%                              | 6/206, 2.9%                      |
| WOMAC-S subscale (0-20)    | Traditional WOMAC           | 1/206, 0.5%                     | 8/206, 3.9%                      | 1/206, 0.5%                     | 11/206, 5.3%                     |
| WOMAC-F subscale (0-170)   | Traditional WOMAC           | 0%                              | 2/206, 1%                        | 0%                              | 1/206, 0.5%                      |
| ShortMAC-F subscale (0-70) | ShortMAC                    | 0%                              | 4/206, 1.9%                      | 0%                              | 4/206, 1.9%                      |

Abbreviations: F, function; P, pain; S, stiffness; ShortMAC, shortened version of the Western Ontario and McMaster Universities Osteoarthritis Index; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

The baseline WOMAC values and the extent of change are consistent with those reported previously in studies looking at nonsurgical treatment of OA of the lower extremity,<sup>5,30,32</sup> supporting the external

validity of our MIC estimates. Williams et al<sup>30</sup> reported the MIC for the WOMAC at 2 months to be 4.0 (0-100 scale) using the Youden index to identify the MIC estimate (sensitivity and specificity equally weight-

ed), or 8.8 when using a specificity value of 0.80. Those MIC values, and those found in the current study, are lower than the 14 to 22 points reported by Escobar et al<sup>12</sup> (0-100 scale) in individuals undergoing

total joint replacement and, therefore, in whom larger changes would be expected. They also used a different anchor question with larger steps.

The MICs corresponding to small, medium, and large self-perceived changes were remarkably stable for both instruments. The ShortMAC demonstrated appropriate stepwise increases in the MIC for increasing levels of the GROC, which were less evident for the full WOMAC version. This is likely due to reduced item redundancy and can be interpreted as evidence of greater sensitivity to change of the ShortMAC. Because we used a 15-point scale in the GROC, the numbers of respondents per scale point were relatively small (eg, only 12 of 206 participants reported feeling “moderately better”); however, categorizing the GROC responses into 3 levels of change ensured sufficient numbers at each level (TABLE 2), giving us the ability to show the extent of MIC improvement across levels of patient-perceived change.

One of the limitations of this research that must be considered is the anchor used in the present study, the GROC instrument, which asked participants to compare the current impact of OA on their overall health status to its impact 9 weeks earlier and at baseline. Although the GROC has been shown to reflect a bias toward current status rather than equally weighting both current and baseline components of “change,”<sup>18,23,24</sup> it is still the recommended reference anchor for MIC studies.<sup>2,11,16,27</sup> Also, it captures more domains of health status than merely pain and physical function, so it does not correlate exactly with the WOMAC. Also, as with any self-reported questionnaire, the GROC is limited by the accuracy of patients’ recall, so it is not recommended for use in clinical practice or for other applications with differing periods of recall.<sup>23,24</sup> In this study, the recall time was consistent between the 2 instruments, and a 9-week recall period is short enough to not be considered problematic.<sup>26</sup> The MIC estimates were lower than the MDC<sub>90</sub>, limiting the interpreta-

tion of the MIC for individual patients.<sup>11</sup> However, the test-retest scores used to calculate the SEM and MDC<sub>90</sub> were conducted 9 weeks apart and, while ideal for estimating the MIC, were likely to bias MDC upward. Other sources recommend SEM or  $0.5 \times SD_{\text{change}}$  as another way to estimate real change over measurement variability, the latter of which, in this case, would be 5.4 to 6.9 points.<sup>11,15</sup> Finding the true MDC would require further research specifically assessing test-retest reliability of the instruments in unchanged participants.

As noted previously,<sup>29,32</sup> Cronbach’s alpha was particularly high in the traditional WOMAC, highlighting the apparent redundancy present in the instrument. Reducing the questionnaire decreased this value toward the desired upper limit of .95,<sup>26</sup> thereby producing more favorable internal consistency, but to a lesser extent than had been previously reported.<sup>29,32</sup> A ceiling effect in the traditional WOMAC has been reported following surgical intervention.<sup>9,12,19,21</sup> In the current study, where nonsurgical intervention was applied, the traditional and reduced-form WOMAC instruments and subscales demonstrated an absence of any floor effects, and minimal ceiling effects well within acceptable levels. This is consistent with earlier research, Yang et al<sup>32</sup> also having reported minimal overall floor and ceiling effects after “conservative” treatment.

The patients included in the current study were involved in a trial of nonoperative therapy for OA of the lower limb. While the type of therapy and its efficacy are of little relevance to the objectives of the current study, at the time of recruitment, these participants were deemed to have a wide spectrum of symptom severity, from mild to significantly impaired by OA, but were not on the waiting list for total joint replacement surgery. As such, their disease burden would be expected to cover a broader range but average less than that of patients referred for surgery, and their treatment effects to be less marked than those in patients scheduled for total joint replacement. Both the traditional WOM-

AC and the ShortMAC have the sensitivity to detect change with nonoperative therapy, thereby expanding their applicability beyond surgical intervention studies.<sup>29,32</sup>

Also with regard to generalizability, to aid in comparisons across studies, we reported both the raw scores and results normalized to a 0-to-100 scale. The traditional WOMAC instrument is available in 3 formats: 5-point Likert scale (range, 0-96), 100-mm visual analog scale (range, 0-240), and, as in the current study, 11-point numeric rating scale (range, 0-240).<sup>7</sup> While no systematic differences have been reported between the scales, given these modifications and others adopted in the literature, it is essential that the scale and the score range be clearly defined.<sup>31</sup>

Other studies have proposed short-form versions of the WOMAC, including reducing the number of items in the WOMAC-P subscale, but no consensus has been reached.<sup>10,22,28</sup> This ShortMAC, a reduced version of the WOMAC, is the only reduced version to have been independently tested in both surgical and nonsurgical patient populations, and for which MIC estimates are available.<sup>29,32</sup>

## CONCLUSION

THE RESULTS OF THIS STUDY SUPPORT recommendation of the reduced-form WOMAC as a patient-friendly alternative to the traditional WOMAC instrument to assess the impact of OA on a patient’s daily life, and as a valid and responsive means of assessing change in status following surgical or nonsurgical intervention. ●

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## APPENDIX

### THE MOA TRIAL TEAM

| Name                                             | Role on Trial Team                             | Contribution                                                                                 | Affiliation                              |
|--------------------------------------------------|------------------------------------------------|----------------------------------------------------------------------------------------------|------------------------------------------|
| Professor J. Haxby Abbott                        | Principal investigator                         | Conception, design, protocols, coordination, monitoring, analysis, interpretation, reporting | University of Otago                      |
| Professor A. John Campbell (deceased)            | Coinvestigator, consultant geriatrician        | Design, coordination, interpretation                                                         | University of Otago                      |
| Associate Professor M. Clare Robertson (retired) | Coinvestigator                                 | Economic evaluation, design, protocols, coordination, monitoring, interpretation             | University of Otago                      |
| Professor G. David Baxter                        | Coinvestigator                                 | Coordination, monitoring                                                                     | University of Otago                      |
| Professor Jean-Claude Theis                      | Coinvestigator, consultant orthopaedic surgeon | Coordination, monitoring, recruitment                                                        | University of Otago                      |
| Professor Paul Hansen                            | Health economist                               | Design and interpretation                                                                    | University of Otago                      |
| Dr Joanne E. McKenzie                            | Statistician                                   | Protocol design                                                                              | University of Otago<br>Monash University |
| Debra McNamara                                   | Research nurse                                 | Participant recruitment and screening                                                        | University of Otago                      |
| Dr Catherine Chapple                             | Outcome assessor                               | Design of intervention protocols                                                             | University of Otago                      |
| Dr Daniel Pinto                                  | Outcome assessor                               | Design of intervention protocols                                                             | University of Otago                      |
| Dr Alexis Wright                                 | Outcome assessor                               | Design of intervention protocols                                                             | University of Otago                      |
| Martin Kidd                                      | Physical therapist                             | Intervention protocol design and delivery                                                    | University of Otago                      |
| Chris Higgs                                      | Physical therapist                             | Intervention protocol design and delivery                                                    | University of Otago                      |
| Jessica Smith                                    | Physical therapist                             | Intervention protocol design and delivery                                                    | University of Otago                      |

Associate members: acknowledgment and thanks to the following for contributions:

| Name                           | Contribution                                                             | Affiliation                                   |
|--------------------------------|--------------------------------------------------------------------------|-----------------------------------------------|
| Professor Peter Herbison       | Statistical design advice                                                | University of Otago                           |
| Professor Jeffrey Basford      | Research advisor, design                                                 | Mayo Clinic                                   |
| Professor G. Kelley Fitzgerald | Research and clinical advisor, design, interventions                     | University of Pittsburgh                      |
| Professor Timothy Flynn        | Research and clinical advisor, design                                    | Regis University<br>Rocky Mountain University |
| Professor Julie Fritz          | Research advisor, design                                                 | University of Utah                            |
| Dr Deidre Hurley-Osing         | Research advisor, design                                                 | University College Dublin                     |
| Dr Julie Whitman               | Clinical advisor, design                                                 | Regis University                              |
| Dr Steve Tumilty               | Physical therapist, intervention delivery                                | University of Otago                           |
| Dr Ewan Kennedy                | Physical therapist, intervention delivery                                | University of Otago                           |
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# The Influence of Patient Choice of First Provider on Costs and Outcomes: Analysis From a Physical Therapy Patient Registry

Neck and back pain conditions are common in general medical practice, are associated with notable morbidity, and are the first and fourth conditions, respectively, leading to the greatest number of years lived with disability.<sup>16,23,35</sup> Approximately \$85 billion are spent annually on spine-oriented conditions,<sup>32</sup> and an additional \$10 to \$20 billion are attributed to economic losses

in productivity each year.<sup>13</sup> Per-patient costs have increased by 49% from 1997 to 2006, with outpatient expenditures showing the greatest increases.<sup>33</sup> From 1997 to 2005, the total estimated expenditures among respondents with spine problems increased by 65%, a higher rate than other non-spine-related health expenditures. Despite the rising costs, there has been no real improvement in terms of disability or reduction in the proportions of individuals who report back or neck pain.<sup>2</sup> The estimated proportion of persons with back or neck problems who self-report physical functioning limitations increased from 20.7% to 24.7% from 1997 to 2005, suggesting that current care models may be insufficient.<sup>32</sup>

This lack of notable improvement in patient outcomes and health expenditures may be due to the type and timing of care provided. First, practitioners commonly use treatment methods that provide nominal to no effect toward recovery and approaches that have been shown to be ineffective or, at best, marginally effective in recovery from spine-related pain.<sup>24,47</sup> Second, poor or delayed access to appropriate care may adversely impact resolution of spine conditions.<sup>25</sup> Traditional health care processes associated with treatment

● **STUDY DESIGN:** Retrospective study.

● **BACKGROUND:** Alternative models of care that allow patients to choose direct access to physical therapy have shown promise in terms of cost reduction for neck and back pain. However, real-world exploration within the US health care system is notably limited.

● **OBJECTIVES:** To compare total claims paid and patient outcomes for patients with neck and back pain who received physical therapy intervention via direct access versus medical referral.

● **METHODS:** Data were accessed for patients seeking care for neck or back pain ( $n = 603$ ) between 2012 and 2014, who chose to begin care either through traditional medical referral or direct access to a physical therapy–led spine management program. All patients received a standardized, pragmatic physical therapy approach, with patient-reported measures of pain and disability assessed before and after treatment. Patient demographics and outcomes data were obtained from the medical center patient registry and combined with total claims paid calculated for the year after the index claim. Linear mixed-effects modeling was used to analyze group differences in pain and disability, visits/time, and annualized costs.

● **RESULTS:** Patients who chose to enter care via the direct-access physical therapy–led spine management program displayed significantly lower total costs (mean difference, \$1543; 95% confidence interval: \$51, \$3028;  $P = .04$ ) than those who chose traditional medical referral. Patients in both groups showed clinically important improvements in pain and disability, which were similar between groups ( $P > .05$ ).

● **CONCLUSION:** The initial patient choice to begin care with a physical therapist for back or neck pain resulted in lower cost of care over the next year, while resulting in similar improvements in patient outcomes at discharge from physical therapy. These findings add to the emerging literature suggesting that patients' choice to access physical therapy through direct access may be associated with lower health care expenditures for patients with neck and back pain.

● **LEVEL OF EVIDENCE:** Economic and decision analyses, level 4. *J Orthop Sports Phys Ther* 2018;48(2):63-71. Epub 26 Oct 2017. doi:10.2519/jospt.2018.7423

● **KEY WORDS:** *alternative payment model, direct access, low back pain, neck pain*

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of spine conditions in the United States often involve screening by a primary care medical physician. Clinical practice guidelines for primary care management of spinal conditions generally suggest initial management strategies of self-care and nonsteroidal anti-inflammatory medications. Referral to specialists, including physical therapists, or for diagnostic imaging is only encouraged for those who fail to respond after a period of watchful waiting.<sup>9,10</sup> Recommended best practices based on such clinical practice guidelines are to avoid bed rest, to use opioid medications for a limited time, and to obtain magnetic resonance imaging only for specific presentation of radicular symptoms.<sup>11,39,42</sup> However, the delivery of inappropriate treatments remains a common occurrence in traditional medical care models.<sup>3,18</sup> In contrast, alternative care models offering direct access (the ability to seek and receive the examination, evaluation, and intervention by a physical therapist without requiring physician referral for legal or insurance coverage) to physical therapy have suggested fewer days of care and lower costs.<sup>4,7,22</sup> These savings are thought to be due to quicker initiation of physical therapy and matching of active treatment strategies to patient presentation.<sup>3,9,10,18,25</sup>

Direct access to physical therapy has been proposed as a potential care model that would favorably impact the outcomes and costs associated with back and neck pain.<sup>4,30,34,38,45</sup> While all 50 states allow some form of direct access to physical therapy, barriers remain, including hospital and care organization policies, insurance coverage, and patient education.<sup>4,36</sup> However, value-based payment initiatives designed to provide patients the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors, are gaining ground.<sup>40,41</sup>

At present, there is little evidence on the influence that direct access to physical therapy may have on the cost-effectiveness and clinical outcomes in

a real-world medical model for back or neck pain. Thus, the objective of this study was to compare patient outcomes and annualized total cost for patients with back and neck pain who had the option to choose either (1) direct access or (2) traditional medical referral to a physical therapy–led spine management program. We hypothesized that we would observe differences in cost but similar outcomes across patients seeking care for spine-related pain and disability.

## METHODS

### Reporting Guidelines

**T**HIS STUDY FOLLOWED THE REPORTING of studies Conducted using Observational Routinely collected Data (RECORD) initiative.<sup>1</sup> Key elements of the RECORD initiative include an explanation of merging of databases, appropriate description of codes used in the study, information on data cleaning and methods of data removal, and eligibility of data, including how data were retained and analyzed for applicability.<sup>29</sup>

### Study Design

The study was a retrospective, nonrandomized, comparative analysis between consecutive patients who began and completed their physical therapy episode of care between January 1, 2012 and December 31, 2013, and between those who chose direct access to physical therapy and those who chose traditional medical care and then were referred to a physical therapy–led spine management program. Baseline patient and clinical data were extracted from the ATI Patient Outcomes Registry, which is registered with ClinicalTrials.gov (NCT02285868) and the US Department of Health and Human Services Agency for Healthcare Research and Quality in the Registry of Patient Registries (2608). Total claims paid were provided by a third-party aggregator from BlueCross BlueShield of South Carolina. The study was approved by the Institutional Review Board of Greenville Health System (GHS), Greenville, SC.

### Clinical Program

Beginning in 2012, a private physical therapy organization partnered with GHS and Steadman Hawkins Clinic of the Carolinas to create a back and neck care delivery program designed to offer alternative opportunities to access treatment for back and neck pain. The program offered adult beneficiaries (those 18 years of age and older) with low back- or neck-related complaints the alternative option to choose physical therapy as their first line of treatment, in contrast to the traditional model of first being seen by a primary care physician. The plan encouraged patients to access physical therapy services earlier than traditional options in their episode of care via health plan communications. Under this program, plan benefits for physical therapy, whether received through direct access or medical referral, were the same. Access to this program was through 1 of 8 clinics colocated within GHS-Steadman Hawkins clinics throughout a 3-county region in the greater Greenville metropolitan area.

### Patient Choice to Access Care

All GHS employees and adult dependents (aged 18 years and older) were eligible for the program. All patients who chose to participate in the back and neck program accessed care in the physical therapy–first model or via traditional medical referral at 1 of 8 physical therapy clinics. Participation in the back and neck program required utilization of physical therapy from 1 of these 8 clinics. The pilot back and neck program provided no limitation for severity, duration of symptoms, or type of symptoms. The program was highlighted in the benefit materials as well as marketed via the employer's internal website, e-mails, flyers, internal newsletters, and department meetings.

### Treatment Procedures

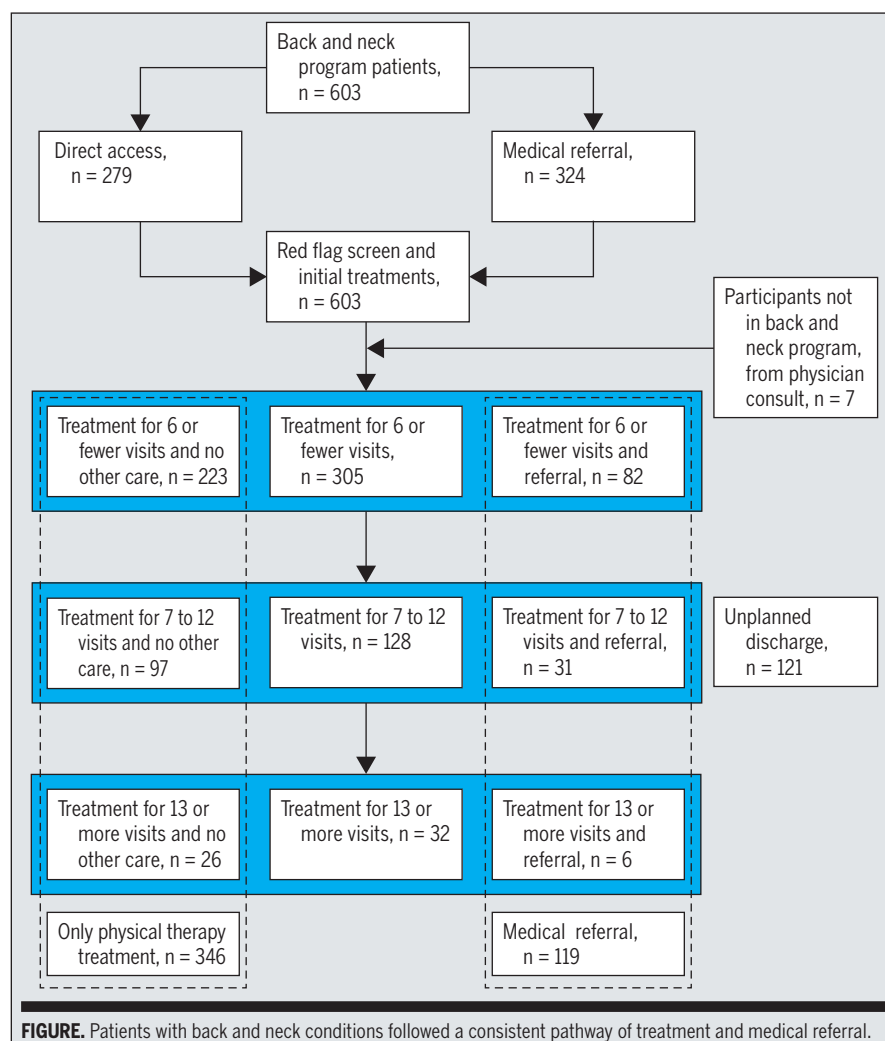
Physical therapy for this program was provided across the 8 select clinics in Greenville, SC by a team of trained physical therapists. Prior to the initiation of the program, a 1-day training session was

conducted with all participating physical therapists. Training emphasized medical screening, treatment-based classification, clinical practice guidelines for neck and back pain, and clinical progression of the program (FIGURE).<sup>5,6,14,20</sup>

Patients were screened for appropriateness of physical therapy intervention by a standardized intake questionnaire. If patients presented with unexplained red flag findings, an on-site physician was consulted for clearance or determination of further medical management. Once deemed appropriate, patients were treated with active procedures, including spinal manipulation, therapeutic exercise, and patient education, based on recently advocated guidelines.<sup>5,14</sup> Training included criteria for progression in an effort to identify nonresponders, using a benchmark of 50% improvement (change from baseline to follow-up) within 6 treatment sessions on the primary disability measures (Oswestry Disability Index [ODI] and/or Neck Disability Index [NDI]). Patients who continued to demonstrate the benchmark improvement (50% reduction) could be approved for 6 more treatment sessions, up to a total of 18. If patients failed to meet a 50% improvement benchmark after 12 treatment sessions or were not satisfied with their progression, a consultation with a senior physical therapist and fellowship-trained spine surgeon or physical medicine and rehabilitation physician was scheduled to determine the need for further medical treatment. Based on this consultation, a medical plan was recommended that may have included further imaging, injections, surgery, or referral to pain management. On rare occasions, patients were seen for physical therapy and pain management beyond the 18th visit (less than 2% of cases).

### Patient Measures

Patients completed baseline descriptive information and self-reported outcome measures for pain (numeric pain-rating scale [NPRS]), disability (ODI or NDI), psychosocial features (Patient Health



**FIGURE.** Patients with back and neck conditions followed a consistent pathway of treatment and medical referral.

Questionnaire [PHQ-4]), and overall health status (European Quality of Life-5 Dimensions [EQ-5D]) as part of their standard course of care. The descriptive information included primary and secondary diagnosis (categorized as neck, neck and arm, back, back and leg, or widespread), sex, age, duration of symptoms, and pain characteristics (eg, multi-regional and/or referred pain), as well as duration of this episode of spine pain.

**The NPRS** An 11-point (0-10) NPRS was used in the study. The NPRS has demonstrated good reliability and validity, with a minimal clinically important difference (MCID) of 2 points for patients with low back pain<sup>8</sup> and 1.3 points for those with neck pain.<sup>12</sup>

**The EQ-5D** The EQ-5D is a generic measure of health status that has demonstrated acceptable levels of content validity. It also has moderate to good correlation with the Pain Disability Index, Roland-Morris Disability Questionnaire, and NPRS in patients with chronic low back pain.<sup>27</sup> Additionally, the EQ-5D is recommended for use in cost-effectiveness analyses.<sup>46</sup>

**The PHQ-4** The PHQ-4 is a measure of anxiety/depressive symptoms that has demonstrated good association with functional impairment, disability days, and health care use.<sup>28</sup> Scores range from 0 to 12, with higher values representing higher levels of anxiety and depression.

**The NDI** Raw score values, which range from 0 (no disability) to 50 (totally dis-

abled), for the NDI were captured. The NDI has demonstrated good to excellent reliability and has published MCIDs ranging from 5 to 9.5 points (out of 50) or 10% to 19% from baseline.<sup>12,49</sup>

**The ODI** Raw score values, which range from 0 (no disability) to 50 (totally disabled), for the ODI were captured. The ODI has demonstrated good reliability and validity and has a reported MCID of 5 points (out of 50) or 10% from baseline.<sup>37</sup>

Follow-up visits allowed systematic capture of outcome measures every 6 treatment sessions and at discharge. Patients were considered off protocol if they did not return for a follow-up treatment session to physical therapy, resulting in an unplanned discharge (n = 83). Patients attending fewer than 6 treatment sessions without a second set of self-reported measures were also considered off protocol and were not included in the analysis (n = 38). These 2 groups of patients represented 121 of 156 patients missing data and were not included in the analyses.

## Cost Measures

Total adjudicated claims from BlueCross BlueShield of South Carolina were acquired from Milliman (Seattle, WA), a third-party aggregator, using its health cost guidelines for all patients who participated in the pilot back and neck program from 2012 to 2014. Total costs were calculated for all claims, including medications, imaging, surgery, physical therapy, and any other service approved by BlueCross BlueShield of South Carolina with an associated primary back or neck ICD-9 code. Total costs were annualized for all patients from the index back or neck claim, then summed for the next 365 days. Patients without 1 year of follow-up claims data were not included in the study. Total costs were then summarized and categorized from the provided health cost guidelines into physical therapy, surgical (spine injections, anesthesia, and surgery), radiology, and all other costs.

## Data Preparation and Reduction

Patient demographics, self-reported outcomes, and clinical data were merged from the ATI Physical Therapy Patient Outcomes Registry with total claims paid by health economists who were not involved in the data-collection or patient treatment processes. The patients' common medical record number, date of birth, and full name were used to merge the patient outcomes, clinical data, and claims files into a single analytical file. In total, 603 patients participated in the pilot program over the 2-year period, and, of those, 447 had unique total claims and patient outcomes data that allowed for retrospective comparison.

Missing values were analyzed and Little's missing-completely-at-random tests were run for variables with missing values. Complete data were present in 95.4% of all outcome variables. All claims data were 100% complete. The ODI/NDI data presented with 17.7% missing values, and pain data presented with 19% missing values. Little's missing-completely-at-random test resulted in a *P* value of .64, suggesting that the data were missing at random. As such, we elected not to impute data.

Adverse events were tabulated by evaluation of all patients' medical charts and confirmed by claims review, including

**TABLE 1**

**PATIENTS REMOVED FROM THE DATA SET AND THOSE INCLUDED IN THE FINAL ANALYSIS\***

| Variable                             | Removed (n = 156) | Included (n = 447) | P Value |
|--------------------------------------|-------------------|--------------------|---------|
| Mechanism of referral, n             |                   |                    | <.01    |
| Direct access                        | 108               | 171                |         |
| Medical referral                     | 48                | 276                |         |
| Age, y                               | 45.4 ± 11.9       | 45.9 ± 11.8        | .69     |
| Sex, n                               |                   |                    | .47     |
| Female                               | 117               | 322                |         |
| Male                                 | 39                | 125                |         |
| Primary diagnosis, n                 |                   |                    | <.01    |
| Neck                                 | 47                | 149                |         |
| Low back                             | 83                | 288                |         |
| Both                                 | 26                | 10                 |         |
| Secondary diagnosis, n               |                   |                    | <.01    |
| Neck                                 | 33                | 102                |         |
| Neck and arm                         | 14                | 49                 |         |
| Back                                 | 51                | 186                |         |
| Back and leg                         | 31                | 75                 |         |
| Widespread                           | 27                | 33                 |         |
| Missing                              | 0                 | 2                  |         |
| Duration of symptoms, n <sup>†</sup> |                   |                    | <.01    |
| Acute                                | 32                | 115                |         |
| Subacute                             | 13                | 74                 |         |
| Chronic                              | 111               | 258                |         |
| Raw baseline ODI/NDI (0-50)          | 13.4 ± 7.4        | 13.9 ± 8.3         | .51     |
| Baseline EQ-5D (-0.109-1.00)         | 0.7 ± 0.2         | 0.7 ± 0.2          | .25     |
| Baseline PHQ-4 (depression) (0-6)    | 1.5 ± 2.1         | 1.5 ± 2.1          | .99     |
| Baseline NPRS (0-10)                 | 5.1 ± 2.4         | 6.0 ± 2.2          | <.01    |

Abbreviations: EQ-5D, European Quality of Life-5 Dimensions; NDI, Neck Disability Index; NPRS, numeric pain-rating scale; ODI, Oswestry Disability Index; PHQ-4, Patient Health Questionnaire-4. \*Values are mean ± SD unless otherwise indicated.

<sup>†</sup>Acute is defined as onset of symptoms within 30 days, subacute is defined as 31 to 180 days since onset of symptoms, and chronic is defined as greater than 180 days since onset of symptoms.

emergency department visits and ICD-9 codes indicating fracture or traumatic injury. We adopted the World Health Organization's definition of an adverse event as "an injury from the medical management, in contrast to complications of the disease."<sup>50</sup> Assessment of adverse events was tallied by the primary author based on postdischarge retrospective chart review.

## Data Analysis

All analyses were performed using SPSS Version 23.0 (IBM Corporation, Armonk, NY). Baseline characteristics between the 156 patients removed from the analysis and the 447 who were included were

evaluated using *t* tests for continuous measures and chi-square tests for nominal variables (TABLE 1). A chi-square test was used to compare proportions of direct access to medical referral across the 8 clinics.

Comparative analysis for self-report, visits, days in care, and claims-related data was performed with linear, mixed-effects models. We used a linear mixed-effects model because it is flexible in analyzing data assumed to be missing at random, it is robust to all forms of covariates, and it can accommodate multiple measures per patient.<sup>48</sup> Group assignment was the fixed-effect variable of interest. For all linear mixed-effects anal-

yses, we included the covariates of age, primary and secondary diagnoses (categorized as neck, neck and arm, back, back and leg, or widespread), and duration of symptoms. Results were reported as estimated marginal means, 95% confidence intervals (CIs), and mean differences.

## RESULTS

### Descriptive Findings

A TOTAL OF 603 INDIVIDUALS WERE analyzed for differences between those removed because of unavailable cost (*n* = 35) or discharge outcomes data (*n* = 121) and those kept in the data set with outcomes and cost data (*n* = 447) (FIGURE). Patients without complete data were more likely to be seen through direct access (physical therapy first), were more likely to have concurrent neck and low back pain, had a more chronic condition, and reported a lower level of pain (TABLE 1).

The majority of the 447 patients included in the analysis chose traditional medical referral (61.7%). Patients who chose traditional medical referral were younger (*P* = .02), more likely to have acute onset of symptoms (*P* < .01), and more likely to have widespread pain (*P* = .04) compared to those who chose direct access to physical therapy (TABLE 2). Regardless of how patients accessed the structured physical therapy program, 79% completed the program without further medical referral (FIGURE). Overall, patients displayed good clinical improvement in disability (mean improvement from baseline, 54%; 95% CI: 46%, 62%) and pain (mean difference, 4 points; 95% CI: 1, 7 points), with no differences between groups (*P* > .05). There was no difference in proportion of direct access to medical referral patients across clinics (*P* > .05) (TABLE 3).

### Self-Report Health Outcomes, Visits/Care Time, and Cost Analyses

When controlling for baseline factors, patients who chose to access care via direct access to physical therapy, compared to those who chose to access care via medi-

TABLE 2

BASILINE CHARACTERISTICS OF PATIENTS ENROLLED IN THE PILOT BACK AND NECK PROGRAM (N = 447)\*

| Variable                          | Full Cohort (n = 447) | Physician Referral (n = 276) | Direct Access to Physical Therapy (n = 171) | P Value |
|-----------------------------------|-----------------------|------------------------------|---------------------------------------------|---------|
| Age, y                            | 45.9 ± 11.8           | 44.9 ± 12.3                  | 47.5 ± 10.8                                 | .02     |
| Sex, n                            |                       |                              |                                             | .67     |
| Female                            | 322                   | 201                          | 121                                         |         |
| Male                              | 125                   | 75                           | 50                                          |         |
| Primary diagnosis, n              |                       |                              |                                             | .05     |
| Neck                              | 149                   | 99                           | 50                                          |         |
| Low back                          | 288                   | 174                          | 114                                         |         |
| Both                              | 10                    | 3                            | 7                                           |         |
| Secondary diagnosis, n            |                       |                              |                                             | .04     |
| Neck                              | 102                   | 61                           | 41                                          |         |
| Neck and arm                      | 49                    | 40                           | 9                                           |         |
| Back                              | 186                   | 112                          | 74                                          |         |
| Back and leg                      | 75                    | 46                           | 29                                          |         |
| Widespread                        | 33                    | 16                           | 17                                          |         |
| Missing                           | 2                     | 1                            | 1                                           |         |
| Duration of symptoms, n†          |                       |                              |                                             | <.01    |
| Acute                             | 115                   | 87                           | 28                                          |         |
| Subacute                          | 74                    | 39                           | 35                                          |         |
| Chronic                           | 258                   | 150                          | 108                                         |         |
| Baseline ODI/NDI (0-50)           | 13.9 ± 8.3            | 13.6 ± 8.1                   | 14.3 ± 8.8                                  | .37     |
| Baseline EQ-5D (-0.109-1.00)      | 0.7 ± 0.2             | 0.7 ± 0.2                    | 0.7 ± 0.2                                   | .28     |
| Baseline PHQ-4 (depression) (0-6) | 1.5 ± 2.1             | 1.4 ± 2.2                    | 1.5 ± 1.7                                   | .72     |
| Baseline NPRS (0-10)              | 6.0 ± 2.2             | 6.0 ± 2.2                    | 5.9 ± 2.2                                   | .42     |

Abbreviations: EQ-5D, European Quality of Life-5 Dimensions; NDI, Neck Disability Index; NPRS, numeric pain-rating scale; ODI, Oswestry Disability Index; PHQ-4, Patient Health Questionnaire-4.

\*Values are mean ± SD unless otherwise indicated.

†Acute is defined as onset of symptoms within 30 days, subacute is defined as 31 to 180 days since onset of symptoms, and chronic is defined as greater than 180 days since onset of symptoms.

cal referral, did not display any significant differences in self-report outcomes for disability or pain ( $P > .05$ ). Patients accessing care via physical therapy direct access had significantly fewer physical therapy treatment sessions ( $P = .04$ ) and days in care ( $P = .03$ ), and lower physical therapy costs ( $P < .01$ ), radiology costs ( $P = .01$ ), other costs ( $P < .01$ ), and total costs ( $P = .04$ ). On average, each patient seen through physical therapy direct access cost the third-party payer \$1543 less than a patient who accessed care via traditional medical referral (TABLE 3).

### Adverse Events and Referral to Orthopaedics

Of patients seeking care via direct access, there were 3 patients with signs and symptoms of upper extremity nerve entrapment who were referred to orthopaedics. There were 4 patients with non-spine-related signs and symptoms who were referred to orthopaedics (3 with hip osteoarthritis), and 1 to primary care (ultimate oncology diagnosis). There were no adverse events noted in patients' charts or via claims review that would suggest a missed condition following the initial physical therapy evaluation. Of the 119 patients who received physical therapy and were sent for medical

referral, 36 patients did not return to the program: 13 after 6 sessions, 15 after 12 sessions, and 8 after 13 sessions or more. The proportions of patients referred for further orthopaedic consult were similar between those seen through physical therapy direct access and patients seen through medical referral.

## DISCUSSION

OUR RESULTS SUGGEST THAT PATIENTS' initial choice of direct access to physical therapy services through a physical therapy-led spine management program results in less total cost of care with comparable outcomes at discharge. Patients in our study who chose direct access to physical therapy for back or neck pain, compared to traditional medical referral, incurred \$1543 less in health care expenses in the year following the start of care. Our results appear to indicate that patients who chose to seek care beginning with physical therapy showed similar improvements in pain and disability, without increased risk, while incurring significantly less annual cost than those who received similar physical therapy treatment but through traditional medical referral. These findings are pragmatic and reflect the impact

of patient choice to access care for neck and back pain in a real clinical environment, using total claims paid as provided by a third-party provider who was blinded to the self-report outcomes.

The contrast in cost with comparable outcomes appears to be impacted by the patients' choice of how to access care. Total claims paid were an average of \$1543 less per patient for those seen through physical therapy direct access compared to those referred from a physician. This equated to a total claims cost savings of greater than \$250 000 in our sample of 171 patients in the direct-access group. It has been estimated that between 1.5% and 36% of individuals in the United States alone experience low back pain on a yearly basis, thus any cost reductions, even small amounts, are considered potentially important.<sup>26</sup> Because both groups received a similar, evidence-based physical therapy model and were treated by the same group of physical therapists, the cost savings likely reflect the change in the health "process" as an independent variable, a finding that deserves further exploration. Our results suggest that the first provider a patient with neck and back pain sees may influence costs over the subsequent year.

Patients in both groups had similar improvement in pain and disability:

TABLE 3

ADJUSTED OUTCOMES DATA, VISITS/CARE TIME, AND CLAIMS DATA FOR THE PATIENTS ENROLLED IN THE PILOT BACK AND NECK PROGRAM\*

| Variable                                | Mean Referral From Physician<br>(n = 276) <sup>†</sup> | Mean Direct Access (PT First)<br>(n = 171) <sup>†</sup> | Mean Difference <sup>‡</sup> | P Value |
|-----------------------------------------|--------------------------------------------------------|---------------------------------------------------------|------------------------------|---------|
| Pain at discharge (NPRS, 0-10)          | 2.0 (1.7, 2.3)                                         | 2.0 (1.6, 2.4)                                          | 0.0 (-0.4, 0.5)              | .92     |
| Disability at discharge (ODI/NDI, 0-50) | 6.1 (5.2, 6.9)                                         | 5.6 (4.5, 6.7)                                          | 0.5 (-0.6, 1.6)              | .40     |
| Total visits, n                         | 76 (6.8, 8.3)                                          | 6.6 (5.7, 7.5)                                          | 0.9 (0.01, 1.9)              | .04     |
| Total time in care, d                   | 46.9 (39.7, 54.1)                                      | 36.4 (27.4, 45.5)                                       | 10.5 (1.0, 20.0)             | .03     |
| Physical therapy costs                  | 915 (790, 1040)                                        | 655 (499, 812)                                          | 260 (97, 422)                | <.01    |
| Radiology costs                         | 375 (277, 473)                                         | 206 (83, 330)                                           | 169 (41, 297)                | .01     |
| Surgical and injection costs            | 1634 (508, 2760)                                       | 600 (-813, 2013)                                        | 1034 (-434, 2501)            | .17     |
| Other costs                             | 96 (74, 118)                                           | 43 (15, 71)                                             | 53 (24, 82)                  | <.01    |
| Emergency room costs                    | 61 (20, 102)                                           | 37 (-15, 89)                                            | 24 (-30, 78)                 | .38     |
| Total costs                             | 3085 (1939, 4224)                                      | 1542 (108, 2976)                                        | 1543 (51, 3028)              | .04     |

Abbreviations: NDI, Neck Disability Index; NPRS, numeric pain-rating scale; ODI, Oswestry Disability Index; PT, physical therapist.

\*Covariates include age, primary and secondary diagnoses, and duration of symptoms (n = 447).

<sup>†</sup>Values in parentheses are 95% confidence interval. All costs are in US dollars.

an average improvement of more than 50% over the course of care. These results were achieved in an average of  $7.2 \pm 6.7$  treatment sessions, which is similar to previously reported values.<sup>21,31</sup> This is interesting, considering the inclusion of patients with chronic pain (61%) and multiregional pain locations (60%) in this study, in contrast to other studies that excluded these patients.<sup>8,21</sup>

Patients undergoing physical therapy via direct access had on average 1 less visit per episode of care and lower physical therapy costs. Additionally, the larger standard deviations for the number of visits, outcomes, and duration of care suggest that patients who entered through medical referral displayed a more varied response to treatment. This may be due to the slight increase in widespread/multiregional pain, as evidenced by greater proportion of secondary diagnoses in the medical referral group (TABLE 2). However, these patients' average visits were similar (11) to other patients in the medical referral group.<sup>4,7,22</sup> This suggests that time to care and other unmeasured factors might have impacted the response to treatment.

We observed that patients who accessed care via direct access to physical therapy had fewer visits and days in care. Past studies have emphasized the value associated with early, timely care by a physical therapist.<sup>19</sup> Unfortunately, time to care after initial trigger event was not captured. It is interesting to note the total time in care difference of 10 days between modes of access to physical therapy, especially because the patients seen via the medical referral route had significantly more chronic pain and widespread pain as evidenced by a greater proportion of chronic pain in the medical referral group (TABLE 2). These may be important personal preference and expectation factors that influence patients' choice of how to access care as well as their response to treatment, and this should be examined in future studies.<sup>2,17,43,44</sup>

Regardless of the patients' choice of access to care, there were no adverse events, defined as "an injury from the

medical management or absence thereof, in contrast to complications of the disease."<sup>50</sup> When patients chose to see a physical therapist first, there were no identified incidents of missed diagnosis or delays in care as a result of physical therapists' clinical decision making. This suggests that physical therapists utilizing a standardized, evidence-based screening questionnaire can adequately determine appropriateness of physical therapist intervention. This is an important finding, as patient safety is often noted as a counterargument to direct access to physical therapy.<sup>15</sup> In fact, 68% of patients with direct access to physical therapy (versus 74% for those accessing through medical referral) had a resolution of their symptoms without further medical referral, suggesting that direct access to physical therapy should be considered as a first-line intervention for acute or chronic onset of back and neck pain. Finally, the lower costs for the patients seen via direct access, who were treated using an evidence-based approach with progression criteria, allay the concerns for the overutilization of physical therapy services without a hard cap on utilization.

### Limitations

Although there are many strengths to this study, some limitations remain. The findings are limited by the nature of the program and unmeasured factors related to patient choice of how to access care. Only patients with available outcomes and claims data were analyzed (74%), which might have biased the results to patients who completed their physical therapy care. The nature of the program allowed patients to select their entry point to care. Thus, patients in the direct-access group might have self-selected to the physical therapist-managed care due to unmeasured factors. The baseline factors that were different between groups might have biased health utilization outcomes (younger age, more acute onset, and more widespread pain). We also did not have prior claims data available for included patients, limiting our ability to control for

prior health utilization. It is possible that prior utilization influenced the differences between groups and that the observed utilization following the initial care-seeking behavior was a result of the patients' choice in regard to first provider.

## CONCLUSION

IN THIS STUDY, PATIENTS WITH BACK AND neck pain who selected direct access to physical therapy incurred significantly less health care costs in the 1-year period following initiation of care. Regardless of point of access to care, on average, patients displayed a greater than 50% decrease in pain and disability, consistent with results of prior studies that a criterion-based and treatment-based classification approach is effective in a generalized cohort of patients with back and neck pain. These results contribute to a growing body of literature that physical therapists provide high-value care for patients with back and neck complaints. The differences observed, at a minimum, suggest that the availability of the choice to pursue direct access to physical therapy for back and neck pain is safe and provides similar outcomes, with cost savings, compared to those of traditional medical referral. These results warrant further research to explore the patient characteristics and factors associated with care-seeking behavior and the resulting costs incurred when seeking medical care for back and neck pain. ●

### KEY POINTS

**FINDINGS:** The initial choice of a physical therapist via direct access for patients with back and neck pain resulted in lower cost of care over the next year, while yielding similar improvement in patient outcomes.

**IMPLICATIONS:** Our results add to emerging literature suggesting that direct access to physical therapy may be a more cost-effective approach for neck and/or back pain. Future studies should evaluate patient and clinical factors that influence patients' choice of how to access care for neck and back pain.

**CAUTION:** This was a retrospective study of germane clinical and claims data from 1 employer and constrained health system, and only represents patients who participated in a standardized physical therapy program.

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# Cross-cultural Adaptation of the Victorian Institute of Sport Assessment-Achilles (VISA-A) Questionnaire for Spanish Athletes With Achilles Tendinopathy

**A**chilles tendinopathy is a chronic condition characterized by localized pain over the Achilles tendon, usually associated with physical activity and sports.<sup>25</sup> Patients often report morning stiffness in the Achilles tendon and focal tenderness. Symptoms can occur at the midportion or insertion of the tendon,<sup>31</sup> resulting in a decrease in functional capacity and athletic performance.

The reported prevalence of Achilles tendinopathy for active individuals ranges from 9% to 40%, depending on type and level of sport activity,<sup>11</sup> but these data may be even higher due to study limitations.<sup>5</sup>

The underlying pathology suggests a failed healing response of the Achilles tendon, including intratendinous changes evidenced by proper imaging techniques.<sup>8</sup> However, correlation between imaging and clinical symptoms is low.<sup>16</sup> Considering Achilles tendinopathy pathophysiology and its functional impact on active individuals, it is essential to have specific outcomes that can evaluate its functional consequences.<sup>10</sup> Patient-reported outcome measures can be useful for that purpose.<sup>9</sup> In fact, self-reported outcomes may help to assess some aspects of a patient's health status that cannot be directly observed (such as pain or related disability).<sup>16</sup>

The Victorian Institute of Sport Assessment-Achilles (VISA-A) questionnaire was developed as a self-administered tool for assessing the severity of symptoms in English-speaking patients with Achilles tendinopathy.<sup>38</sup> The VISA-A questionnaire rates symptoms related to different tendon-load situations and assesses

- **STUDY DESIGN:** Clinical measurement study.
- **BACKGROUND:** Achilles tendinopathy is a prevalent sport-related injury. The Victorian Institute of Sport Assessment-Achilles (VISA-A) questionnaire is a widely used patient-reported outcome to assess the severity of symptoms for this injury.
- **OBJECTIVE:** To adapt the VISA-A questionnaire into Spanish and to assess its psychometric properties.
- **METHODS:** Cross-cultural adaptation was conducted according to recommended guidelines. The Spanish VISA-A (VISA-A-Sp) questionnaire was administered to 210 subjects: 70 healthy students, 70 active at-risk subjects (participating in running and jumping), and 70 patients diagnosed with Achilles tendinopathy. Participants were assessed at baseline and after 3 to 5 days. The injured subjects were also evaluated with a quality-of-life questionnaire (Medical Outcomes Study 36-Item Short-Form Health Survey [SF-36]) and at discharge. The final VISA-A-Sp was evaluated for reliability, validity, and responsiveness.
- **RESULTS:** Cronbach alpha for the VISA-A-Sp was greater than .8. The intraclass correlation coefficient

(model 2,1) was 0.993 (95% confidence interval: 0.991, 0.995;  $P < .05$ ). In the confirmatory factor analysis, a 1-factor solution obtained a relatively good fit. Subjects with Achilles tendinopathy scored significantly lower than the other 2 groups ( $P < .001$ ). The VISA-A-Sp score within the Achilles tendinopathy group showed significant correlations with SF-36 physical components (Spearman  $\rho > 0.5$ ,  $P < .001$ ). The standard error of the measurement was 2.53, and the minimal detectable change at the 95% confidence level was 7 points. The responsiveness indicators included an effect size of 2.16 and a standardized response mean of 1.92.

● **CONCLUSION:** The VISA-A-Sp showed satisfactory psychometric properties that were comparable to the original English-language version. Therefore, it can be recommended for use in clinical practice and research for assessing the severity of symptoms in Spanish-speaking athletes who suffer from Achilles tendinopathy. *J Orthop Sports Phys Ther* 2018;48(2):111-120. Epub 13 Dec 2017. doi:10.2519/jospt.2018.7402

● **KEY WORDS:** Achilles tendinopathy, patient-reported outcome measure, Spanish, validation

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their impact during sports participation. It is considered a valuable outcome for monitoring Achilles tendinopathy symptoms.<sup>22</sup> The VISA-A questionnaire has been adapted into different languages, including Swedish,<sup>41</sup> Italian,<sup>32</sup> Dutch,<sup>12</sup> German,<sup>28</sup> Turkish,<sup>14</sup> Danish,<sup>22</sup> and French.<sup>25</sup> The psychometric properties of these versions of the VISA-A are summarized in **TABLE 1**. Although the use of different translated versions of the VISA-A has increased in both clinic and research settings,<sup>32</sup> development of different versions of this questionnaire remains relevant.<sup>41</sup>

For the proper use of patient-reported outcomes in a different language or culture, a systematic process of adaptation and validation is required.<sup>34</sup> Spanish

is the second worldwide language, with 558 million Spanish speakers.<sup>23</sup> Due to the absence of a tool available in Spanish for evaluating changes in trials including patients with Achilles tendinopathy, the aim of the current study was to translate and cross-culturally adapt the VISA-A questionnaire into Spanish and to assess its psychometric properties in athletes with Achilles tendinopathy.

## METHODS

### Cross-cultural Adaptation

**A**CULTURAL AND LINGUISTIC ADAPTATION of the questionnaire items and subsequent assessment of the psychometric properties of the instrument

were conducted.<sup>34</sup> The translation process was performed following the international recommendations of Beaton et al<sup>3</sup> (**FIGURE 1**).

**Translation and Synthesis** Two independent bilingual persons translated the VISA-A questionnaire from English to Spanish: a sports physical therapist and an expert in English philology without a health sciences background. After both translated versions were completed, a meeting was held to produce a consensus version in Spanish.

**Back Translation** Back translation was also completed independently by 2 native English speakers fluent in Spanish and blinded to the original VISA-A questionnaire: a physical therapist and a native

**TABLE 1**

**PSYCHOMETRIC PROPERTIES OF THE ORIGINAL AND PUBLISHED ADAPTATIONS OF THE VISA-A**

|         | Reliability             |                                                                   |                | Validity                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|---------|-------------------------|-------------------------------------------------------------------|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|         | Internal Consistency    | Test-Retest                                                       | Interval, d    |                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| English | NA                      | Pearson $r = 0.81^*$                                              | 7              | Spearman rho with the Percy-Conochie grade of severity was 0.58, <sup>†</sup> and with the Curwin-Stanish tendon grading system was $-0.57^†$                                                                                                                                                                                                                                                                                                  |
| Swedish | Cronbach $\alpha = .77$ | Patients, $n = 22$<br>Pearson $r = 0.89$ , ICC = 0.89             | 7              | Exploratory factor analysis: 2-factor solution (factor 1, items 1-6: pain/symptoms and factor 2, items 7 and 8: physical activity)<br>Percent variance explained: NA<br>Spearman rho with Stanish grading system was $-0.68^†$                                                                                                                                                                                                                 |
| Dutch   | Cronbach $\alpha = .78$ | Patients, $n = 55$<br>ICC = 0.97 (CI: 0.95, 0.98)                 | 4-5            | Pearson $r$ with the AOFAS was 0.56*; with the VAS for pain and the VAS for function was $-0.54^*$ and 0.50*, respectively; and with the FAOS symptoms, pain, sport, activities of daily living, and quality of life subscales was 0.55* to 0.59*<br>Pearson $r$ was 0.31* to 0.70* with the following SF-36 physical components: PCS, RP, PF, and BP; and was 0.04 to 0.37 with other social and mental dimensions (SF, MH, RE, VT, GHP, MCS) |
| Italian | NA                      | Cohen $\kappa = 0.80$ (CI: 0.70, 0.86)                            | 0 <sup>‡</sup> | NA                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| German  | Cronbach $\alpha = .74$ | Patients, $n = 15$<br>ICC = 0.87                                  | 7              | Spearman rho with the Percy-Conochie grade of severity was 0.95, <sup>†</sup> and with the Curwin-Stanish tendon grading system was $-0.95^†$                                                                                                                                                                                                                                                                                                  |
| Turkish | Cronbach $\alpha = .66$ | Pearson $r = 0.99^*$<br>Split-half reliability coefficient = 0.77 | 7              | Spearman rho with the Stanish et al tendon grading system was $-0.86$ , <sup>†</sup> with the Grimby et al physical activity grading system was 0.74, <sup>†</sup> and with the physical domain of the WHOQOL-BREF was 0.37 <sup>†</sup><br>Spearman rho with the social domain of the WHOQOL-BREF was 0.13 ( $P > .05$ )                                                                                                                      |
| Danish  | Cronbach $\alpha = .73$ | Pearson $r = 0.80^*$<br>ICC = 0.79                                | 2-5            | Achilles tendinopathy patients had a significantly lower score <sup>†</sup> compared with the healthy controls                                                                                                                                                                                                                                                                                                                                 |
| French  | Cronbach $\alpha = .90$ | ICC = 0.99 (CI: 0.996, 0.998)                                     | 0 <sup>‡</sup> | Spearman rho was 0.41* to 0.57* with physical components of the SF-36 (PF, RP, BP, GHP) and moderate to weakly correlated (0.19-0.39*) for mental components (MH, RE, SF, VT)                                                                                                                                                                                                                                                                  |

*Abbreviations:* AOFAS, American Orthopaedic Foot and Ankle Society score; BP, bodily pain; CI, confidence interval; FAOS, Foot and Ankle Outcome Score; GHP, general health perception; ICC, intraclass correlation coefficient; MCS, mental component summary; MH, mental health; NA, not available; PCS, physical component summary; PF, physical functioning; RE, role emotional; RP, role physical; SF, social functioning; SF-36, Medical Outcomes Study 36-Item Short-Form Health Survey; VAS, visual analog scale; VISA-A, Victorian Institute of Sport Assessment-Achilles; VT, vitality; WHOQOL-BREF, World Health Organization Quality of Life-BREF questionnaire.

\* $P < .05$ .

<sup>†</sup> $P < .01$ .

<sup>‡</sup>Twice within 30 minutes.

English teacher without a medical background. A consensus back-translated version was obtained.

**Expert Committee Review** All involved translators, together with the research team members, drafted the final version in communication with one of the original authors.

**Pretesting** The Spanish prefinal version of the VISA-A questionnaire was tested in a preliminary sample of 11 subjects with Achilles tendinopathy (mean  $\pm$  SD age,  $26 \pm 6$  years; 8 men) to assess whether this version was properly understandable and had appropriate vocabulary and proper expressions relevant to the Spanish language and culture.

**Validation Study** Instruments and pro-

cedures used for the validation phase are provided below.

## Participants

A convenience sample of 210 physically active subjects were recruited: 70 healthy students of sport sciences and physiotherapy degrees at Miguel Hernández University practicing sport at least 3 times a week, but without high load to the Achilles tendon (swimming, fitness, rowing, and cycling); 70 subjects who participated at least 3 times per week in sports disciplines with an increased risk for Achilles tendinopathy (running, trail, or basketball); and 70 patients diagnosed with Achilles tendinopathy who belonged to 10 sport clubs and 5 private clinics in Spain.

Inclusion criteria for patients were the presence of a clinical diagnosis of Achilles tendinopathy, with tendon changes verified by ultrasound or magnetic resonance imaging (MRI); being older than 18 years of age; and being able to give written informed consent. For Achilles tendinopathy diagnosis, relevant aspects of the clinical history included history of pain and symptoms related to loading at the midportion of the tendon or at the calcaneal insertion and morning stiffness.<sup>25</sup> Participants were excluded if they had total or partial tendon rupture of the Achilles tendon, other simultaneous or recent injuries in the extremity, previous surgery, Haglund's disease, inflammatory or autoimmune conditions, or pregnancy. In cases of bilateral involvement, the most affected side was considered.

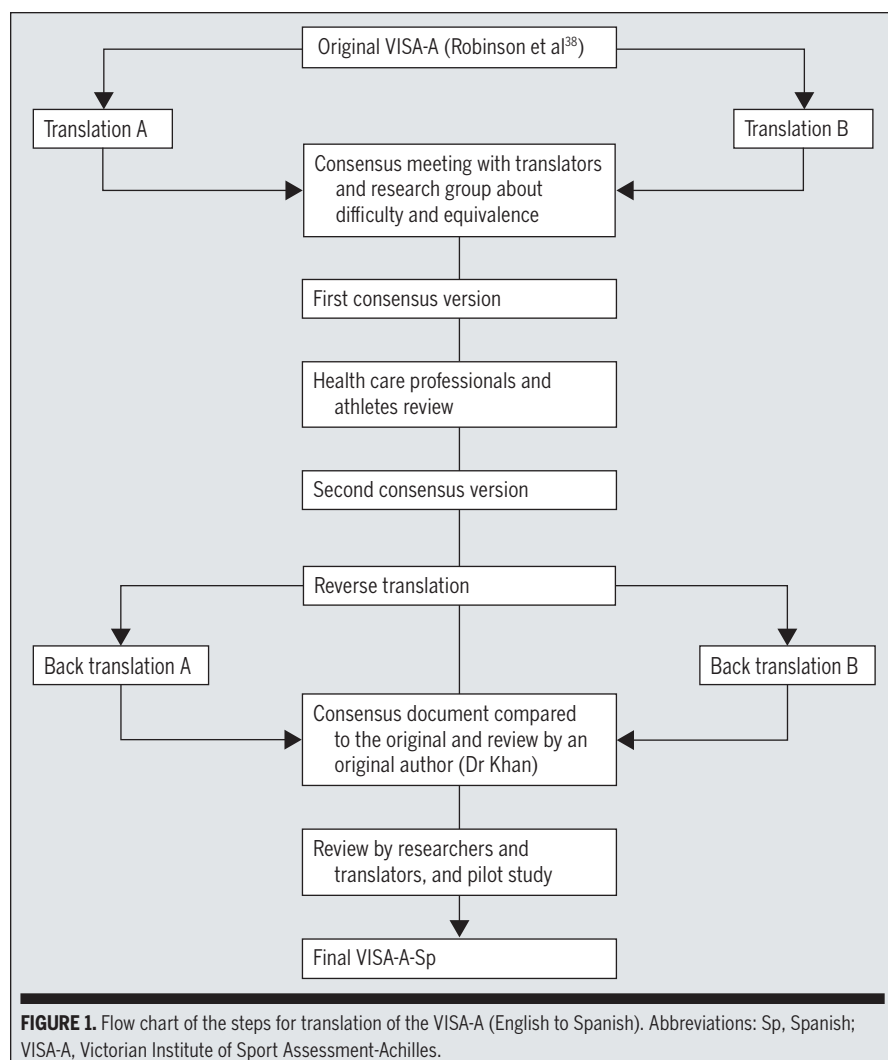
## Instruments

The VISA-A questionnaire consists of 8 items.<sup>38</sup> The first 3 items rate pain or stiffness level on a numeric pain-rating questionnaire (0 to 10); the following 3 items are about pain during daily life activities (items 4 and 5) and the capacity to perform single-leg hops (item 6). The final 2 questions are about the impact of Achilles tendinopathy on sports participation (with categorical response options). The maximum possible score is 100 points, where higher scores are associated with lesser symptoms.

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) Spanish version was used for assessing convergent and divergent validity.<sup>1</sup> It is a generic measure of health status that includes 36 questions distributed across 8 domains: physical function, physical role, bodily pain, general health, vitality, social function, emotional role, and mental health. The scoring ranges from 0 to 100 points, with higher scores indicating better health status.

## Procedure

All participants read and signed an informed-consent form prior to participation. The study protocol was approved



by the Ethics and Experimental Research Committee of Miguel Hernández University (DPC-SHS-001-11). Within healthy and at-risk groups, a member of the research team administered the questionnaires. Patients in the Achilles tendinopathy group were recruited from physical therapy services of 10 different sport clubs (running, athletics, handball, and basketball) and 5 private sport clinics in Spain. The principal investigator (S.H.S.) coordinated the physical therapists to ensure that all procedures were being conducted adequately. Patients were recruited between January 2013 and September 2015.

The assessment of psychometric properties of the VISA-A Spanish version (VISA-A-Sp) was conducted following the COnsensus-based Standards for the selection of health Measurement INSTRuments (COSMIN) initiative.<sup>35</sup>

**Reliability** Reliability refers to both the degree of homogeneity of the questionnaire (internal consistency) as the reproducibility of the scores (temporal stability or test-retest reliability) and the absence of random errors.<sup>43</sup> Both internal consistency and temporal stability were studied in the total sample. For temporal stability evaluation, the VISA-A-Sp questionnaire was administered 3 to 5 days after the first assessment. It was assumed that the clinical status of the participants would not change during this period.<sup>43</sup> Measurement error was assessed in the same units of the questionnaire by calculating the standard error of measurement (SEM) and the minimum detectable change (MDC) in the Achilles tendinopathy group.<sup>13,19</sup> The MDC represents the minimal change that a patient has to exhibit on a questionnaire to ensure that the observed changes are real.<sup>19</sup> The SEM is an estimate of the expected variation in a set of stable scores, assuming that real change has not occurred.<sup>13</sup>

**Validity** Construct validity was studied through the analysis of the factor structure of the VISA-A-Sp questionnaire, using a confirmatory approach. Additionally, to assess convergent validity, correlation coefficients were calculated to check

the relationship between the VISA-A-Sp and the SF-36 domains at baseline. External validity was tested by comparing VISA-A-Sp scores among groups.

For convergent validity, we hypothesized that correlations between scores of the VISA-A-Sp and physical dimensions of the SF-36 (physical functioning, physical role, bodily pain, and standardized physical component summary) would be higher than those correlations of the VISA-A-Sp score with other domains of the SF-36 (vitality, mental health, emotional role, social role, and general health perceptions).

**Responsiveness** For the responsiveness assessment, the VISA-A-Sp and SF-36 questionnaires were completed by each participant with Achilles tendinopathy at baseline and again at discharge or at 3 months (whichever came first) to assess change with physical therapy treatment. In most cases, the treatment included manual therapy, management of the tendon load (eg, exercises, training, and activity modifications), electrotherapy, and ultrasound-guided percutaneous electrolysis.

**Feasibility** Finally, to assess feasibility, we recorded the time that subjects spent filling out the questionnaire. Ceiling and floor effects were also measured, considered present when more than 15% of the responders achieved the theoretical minimum or maximum possible score.

### Statistical Analysis

All statistical analyses were performed with IBM SPSS Statistics 23 (IBM Corporation, Armonk, NY) and EQS 6.1 software.<sup>4</sup> The Kolmogorov-Smirnov test was applied to assess the normal distribution of VISA-A-Sp scores in the total sample and for Achilles tendinopathy patients. For internal consistency, the Cronbach alpha was calculated. Test-retest reliability was studied using the intraclass correlation coefficient (ICC) model 2,1 and 95% confidence interval (CI). A Bland-Altman plot was constructed to show the agreement between individual subjects' scores. It includes a scatter plot of the

differences between the baseline and the second VISA-A applications against their means, with 95% limits of agreement (mean difference  $\pm 1.96 \times SD_{diff}$ ).

Dimensionality was assessed using a confirmatory factor analysis (CFA). Normality was checked using Mardia's normalized kurtosis coefficient and robust maximum-likelihood method. The following fit indexes were used in the CFA: (a) the Satorra-Bentler-scaled chi-square value divided by the degrees of freedom, (b) standardized root-mean-square residual (SRMR), (c) robust comparative fit index (CFI), and (d) root-mean-square error of approximation (RMSEA). A reasonable fit is indicated with an SRMR less than 0.08, a goodness-of-fit index of 0.90 or greater, and RMSEA less than 0.06 (indicating a good fit, whereas values greater than 0.08 represent an adequate fit).<sup>21</sup>

Between-group differences were analyzed using the Kruskal-Wallis test, with a post hoc Dunn test for multiple comparisons. The alpha level was set at .05. Correlation of the VISA-A-Sp scores with the SF-36 domains was calculated using Spearman rho. To compare VISA-A-Sp scores with scores on the original questionnaire and other adapted versions of the VISA-A, we used a 2-sample *t* test.

Effect size and standardized response mean (SRM) statistics were calculated as distribution-based responsiveness indicators and interpreted using Cohen's thresholds.<sup>7</sup> Effect size was calculated as the mean difference between baseline and discharge scores of the Achilles tendinopathy patients, divided by the standard deviation of the baseline scores. The SRM was calculated as the mean change scores divided by the standard deviation of the change scores.<sup>27</sup>

The parameters of error measurement were the SEM and MDC, and they were measured only in the Achilles tendinopathy group. The SEM was calculated as  $SD \times \sqrt{1 - R}$ , where SD is the standard deviation of the first assessment and *R* is the reliability coefficient for the questionnaire. We used the ICC<sub>2,1</sub> of the ten-

dinopathy group, as recommended by Stratford.<sup>42</sup> To calculate MDC threshold at the individual level, we used the following formula:  $MDC_{95} = 1.96 \times \sqrt{2} \times SEM$ , where 1.96 is the value associated with the 95% CI and  $\sqrt{2}$  accounts for the error associated with taking 2 measurements.

For the sample-size estimation, 2 aspects were considered. In the reliability study, for an alpha of .05, a statistical power of 0.80, lower limit  $\rho_{(o)}$  of 0.7, upper limit  $\rho_{(i)}$  of 0.9, and an estimated Spearman  $\rho$  of 0.85, a total sample of 120 subjects was required. In addition, the recommendation of at least 200 cases to perform CFA was followed.<sup>30</sup>

## RESULTS

### Demographics

**T**HE PARTICIPANT DEMOGRAPHIC data and characteristics are presented in **TABLE 2**. Within the Achilles tendinopathy group, mean duration of symptoms was  $12.1 \pm 11.4$  months; it was the first episode for 33% of the patients. The remaining 67% reported 2 (46%) or more (21%) episodes of recurrence. The right side was affected in 60% of the cases. The location of pain was at the body of the Achilles tendon in 64% of cases. Tendinopathy was confirmed with ultrasound in 56% of the patients and with MRI in 44%. Thirty-two of the 70 patients with Achilles tendinopathy had

discontinued their sports activity at the time of the evaluation.

### Translation

No important difficulties were reported during the translation process; however, the research team decided to introduce some changes in the prefinal questionnaire to improve the comprehensibility. In relation to item 2, some participants in the pretesting phase manifested doubts about the specific gesture to which the question refers. To clarify this, we attached a representative image near the item text (**APPENDIX**, available at [www.jospt.org](http://www.jospt.org)).

Additionally, to improve the self-administration, we decided to change the formal presentation of items 2 through 5. We introduced the pain-intensity number in boxes in increasing order and placed the scoring scale under the response boxes, to avoid misinterpretation, because in the original presentation, “no pain” corresponded to the number 10, which was cognitively contradictory for some patients.

### Reliability

For internal consistency, Cronbach alpha was .89 for the first assessment and .88 for the second. When Cronbach alpha was analyzed for the questionnaire by eliminating each item one at a time, it ranged from .87 to .94. For test-retest assessment, ICC was 0.993 (95% CI:

0.991, 0.995;  $P < .001$ ). In individual item analysis, all calculated ICCs ranged between 0.99 and 1.0. A Bland-Altman plot is presented in **FIGURE 2**, showing that the mean difference between the 2 applications of the VISA-A-Sp was -0.63 points (limits of agreement ranging from 4.64 to -5.90 points). The values for SEM and  $MDC_{95}$  at the individual level were 2.53 and 7 points, respectively.

### Construct Validity: Factor Structure

The multivariate and univariate normality assumptions were checked. Range of values for univariate skewness (-1.31 to -0.82) and kurtosis (-0.77 to 1.51) indicated normality. Mardia's normalized multivariate value was 39.38, which indicated nonnormal distribution.

Confirmatory factor analysis was conducted to evaluate the fit of the 1-factor model, and robust statistics were used. Data indicated that the 1-factor model obtained a relatively good fit, with adequate values for Satorra-Bentler-scaled chi-square divided by the degrees of freedom, SRMR, CFI, and RMSEA. Thus, the model was statistically significant ( $\chi^2_{20} = 47.03$ ,  $P < .01$ , but  $\chi^2/df = 2.35$ ). The results for additional fit indexes examined were as follows: SRMR = 0.03, CFI = 0.98, and RMSEA = 0.08 (CI: 0.05, 0.12). Factor loadings for the 1-factor model related to the VISA-A-Sp scores are shown in **TABLE 3**.

### Validity: Group Differences

Mean VISA-A-Sp scores for all groups are shown in **TABLE 4**. The VISA-A-Sp scores exhibited asymmetric distribution ( $Z_{K-S} = 2.4$ ,  $P < .001$ ) when all groups were considered together. The scores in the Achilles tendinopathy group showed a normal distribution. Differences between the VISA-A-Sp scores of the tendinopathy group and both healthy and at-risk groups were significant (43.8 and 38.2 points, respectively;  $P < .01$ ). As shown in **FIGURE 3**, no differences between healthy and at-risk groups were observed (5.6 points,  $P > .05$ ). Scores of the healthy and Achilles tendinopathy groups were

**TABLE 2**

**DESCRIPTIVE CHARACTERISTICS AND VISA-A-Sp SCORES OF THE STUDY POPULATION\***

|                                    | Healthy    | At Risk     | Achilles Tendinopathy |
|------------------------------------|------------|-------------|-----------------------|
| Age, y                             | 20.3 ± 2.8 | 24.1 ± 4.2  | 33.9 ± 12.0           |
| Sex, n                             |            |             |                       |
| Men                                | 60         | 54          | 34                    |
| Women                              | 10         | 16          | 36                    |
| Body mass index, kg/m <sup>2</sup> | 23.3 ± 1.9 | 23.4 ± 1.8  | 23.9 ± 2.4            |
| Training days per week             | 3.7 ± 0.7  | 4.5 ± 1.1   | 5.0 ± 1.1             |
| Training hours per day             | 2.1 ± 0.4  | 2.85 ± 0.40 | 2.8 ± 1.0             |
| First VISA-A-Sp                    | 98.1 ± 1.8 | 92.6 ± 6.4  | 54.4 ± 12.6           |
| Second VISA-A-Sp                   | 98.1 ± 2.0 | 92.3 ± 6.1  | 56.5 ± 12.4           |

Abbreviation: VISA-A-Sp, Spanish version of the Victorian Institute of Sport Assessment-Achilles.

\*Values are mean ± SD unless otherwise indicated.

# RESEARCH REPORT

similar to those reported in previous versions of the VISA-A ( $P > .05$ ), except for individuals for the English and Dutch versions, who scored slightly but significantly higher (TABLE 4).

Convergent and divergent validity was assessed for the Achilles tendinopathy group. Moderate correlations between the VISA-A-Sp score and the following SF-36 domains were found at baseline: physical function ( $r_s = 0.66$ ,  $P < .001$ ), physical role ( $r_s = 0.54$ ,  $P < .001$ ), bodily pain ( $r_s = 0.60$ ,  $P < .001$ ), and standardized physical component summary ( $r_s = 0.58$ ,  $P < .001$ ). However, the VISA-A-Sp score did not show significant correlation with social function ( $r_s = 0.21$ ,  $P > .05$ ), emotional role ( $r_s = -0.05$ ,  $P > .05$ ), general health ( $r_s = 0.11$ ,  $P > .05$ ), vitality ( $r_s = 0.23$ ,  $P > .05$ ), mental health ( $r_s = 0.32$ ,  $P > .05$ ), and standardized mental component summary ( $r_s = 0.03$ ,  $P > .05$ ). At discharge, correlations with the standardized physical and mental component summaries were 0.56 ( $P < .01$ ) and 0.25 ( $P < .05$ ), respectively.

The mean change in the VISA-A-Sp score for the tendinopathy group was  $27.3 \pm 14.4$  points between baseline and discharge applications. There was a moderate and significant correlation with changes in the SF-36 standardized physical component summary score ( $r_s = 0.48$ ,  $P < .01$ ). The effect size was 2.165 and the SRM was 1.923.

## Feasibility

Participants in the study spent less than 5 minutes completing the VISA-A-Sp questionnaire. No patient with Achilles tendinopathy achieved the highest or lowest possible score on the questionnaire. By item, no patient obtained a maximum or minimum score within more than 75% of the population. Therefore, no floor or ceiling effect occurred.

## DISCUSSION

THE MOST IMPORTANT FINDING OF the present study was that the VISA-A-Sp questionnaire is an appropriate instrument to assess symptom

severity in Spanish-speaking athletes with Achilles tendinopathy, in terms of validity and reliability.

Proper monitoring of clinical outcomes is considered essential for evidence-based physical therapy.<sup>2</sup> In order to achieve this professional standard, the use of valid and reliable self-reported out-

comes is an effective strategy.<sup>28</sup> Therefore, to have an appropriate tool for assessing the impact of Achilles tendinopathy in Spanish-speaking active subjects, our objective was to cross-culturally adapt the VISA-A questionnaire into Spanish. Scott et al<sup>39</sup> recommended generating new adapted versions with proper evalu-

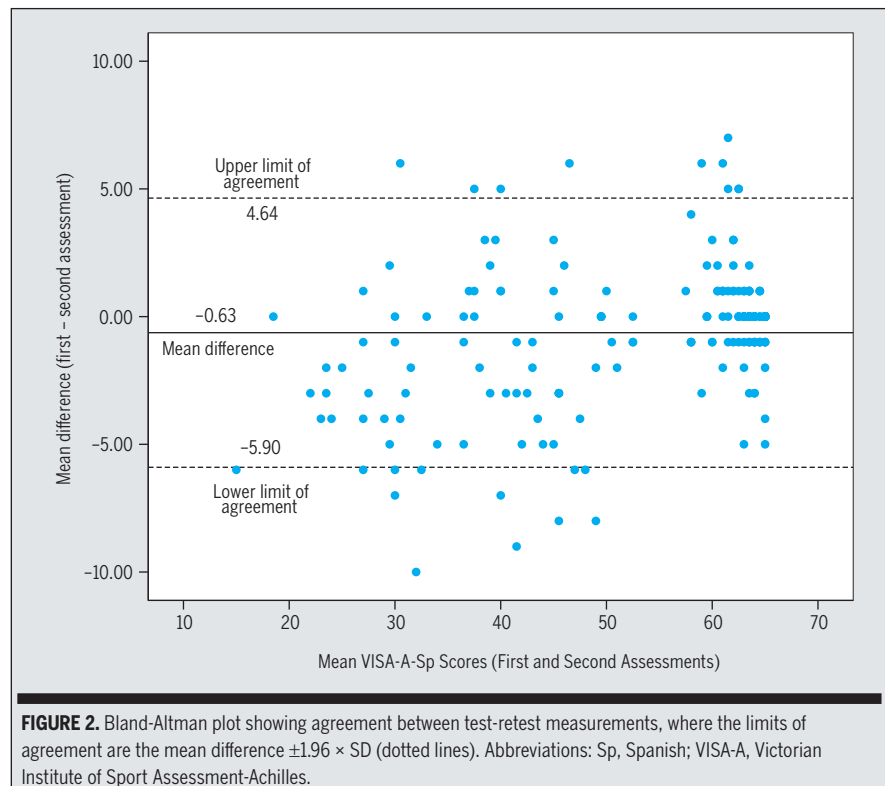


TABLE 3

### FACTOR LOADINGS FOR THE 1-FACTOR SOLUTION IN THE CONFIRMATORY FACTOR ANALYSIS

| VISA-A Questionnaire Items                                                                                                                                                              | Component Loading |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| 1. For how many minutes do you have stiffness in the Achilles region on first getting up?                                                                                               | 0.76              |
| 2. Once you are warmed up for the day, do you have pain when stretching the Achilles tendon fully over the edge of a step (keeping knee straight)?                                      | 0.88              |
| 3. After walking on flat ground for 30 minutes, do you have pain within the next 2 hours? (If unable to walk on flat ground for 30 minutes because of pain, score 0 for this question.) | 0.84              |
| 4. Do you have pain walking downstairs with a normal gait cycle?                                                                                                                        | 0.75              |
| 5. Do you have pain during or immediately after doing 10 (single-leg) heel raises from a flat surface?                                                                                  | 0.86              |
| 6. How many single-leg hops can you do without pain?                                                                                                                                    | 0.91              |
| 7. Are you currently undertaking sport or other physical activity?                                                                                                                      | 0.82              |
| 8. For how long can you manage being physically active?                                                                                                                                 | 0.91              |

Abbreviation: VISA-A, Victorian Institute of Sport Assessment-Achilles.

ation of the psychometric properties as one way to facilitate the use of the VISA-A. After following the recommendations of the COSMIN initiative,<sup>35</sup> we found that the VISA-A-Sp showed good psychometric properties in our sample of Spanish subjects. It is also important to note that we did not find any discrepancies between the English and Spanish versions of the VISA-A, though some changes were introduced in the Spanish version to improve self-administration.

## Psychometric Properties

**Internal Consistency** The Cronbach alpha value obtained for the total sample reflects adequate correlations among the items of the VISA-A questionnaire. It is similar to the French version,<sup>25</sup> and slightly higher than the value obtained in other adaptations, in which Cronbach alpha ranges from .66 to .78.<sup>12,14,22,28,41</sup>

We used the widely accepted cutoff for the Cronbach alpha of .7 or higher.<sup>19</sup> Calculating Cronbach alpha by subtracting single items revealed no significant changes in the overall Cronbach alpha, indicating no item redundancy.

**Reliability** Our results were similar to those of other adapted versions of the VISA-A in which the ICC was used.<sup>12,22,25,28,41</sup> In our assessment of the test-retest reliability, we used a large sample and a time interval of 3 to 5 days between applica-

tions. We considered the time interval proper to prevent recollection of previous answers and short enough for symptoms to vary unsubstantially.<sup>43</sup> In the Bland-Altman plot, the zero line was within the 95% CI of the mean difference between the second and first assessments, confirming that no systematic bias was observed.

**Validity** Mean VISA-A-Sp scores obtained by the healthy and Achilles tendinopathy groups are similar to those for the original version, and no statistically significant differences were found. Scores on the VISA-A questionnaire were able to discriminate between asymptomatic subjects and those with Achilles tendinopathy, but this questionnaire should not be considered as a diagnostic tool.<sup>22,39</sup> For this reason, we did not include a fourth group with other ankle or foot injuries. Ceiling and floor effects did not appear in our study, strengthening the validity of the VISA-A-Sp.

In relation to the construct validity, the factor structure of the VISA-A has seldom been examined in the literature. There are no data on the dimensionality of the original version, and only Silbernagel et al<sup>41</sup> reported results in the Swedish adaptation. Using an exploratory factor analysis in a sample of 51 patients, they found 2 factors: pain/symptoms (items 1-6) and physical activity (items 7-8).

However, our results using a CFA show a unidimensional structure of the VISA-A-Sp underlying the construct “severity of the symptoms.” This topic has also been discussed in the Victorian Institute of Sport Assessment-patella questionnaire.<sup>6,20</sup> This difference in the factor structure of the VISA-A questionnaire between versions could be due to the characteristics of the studied samples.

Measurement error refers to the systematic and random error of a patient’s score that is not attributed to true changes in the concept that is being measured.<sup>19</sup> The SEM and MDC of the VISA-A questionnaire have only been reported for the Dutch version (4.1 and 11.3 points, respectively).<sup>12</sup> We obtained lower values in the Spanish version: 2.53 points for the SEM and 7 points for the MDC<sub>95</sub>. This implies that to determine a real effect of a therapeutic intervention, a change of at least 7 points in the VISA-A-Sp score would be required to indicate that a real change has occurred.<sup>19</sup>

Little information has been reported about the responsiveness of the VISA-A questionnaire.<sup>31</sup> In the current study, the large effect size (greater than 0.8) provides evidence that the VISA-A-Sp can detect changes in symptom severity at 2 different points in the clinical course of Achilles tendinopathy. However, a practical indicator of responsiveness of clinical score changes is the minimum clinically

TABLE 4

VISA-A SCORES FOR DIFFERENT GROUPS  
IN THE AVAILABLE VERSIONS\*

|         | Healthy |              | At Risk |              | Achilles Tendinopathy |              |
|---------|---------|--------------|---------|--------------|-----------------------|--------------|
|         | n       | VISA-A Score | n       | VISA-A Score | n                     | VISA-A Score |
| English | 63      | 96 ± 7       | NA      | NA           | 45                    | 64 ± 17      |
| Swedish | 15      | 96 ± 4       | NA      | NA           | 51                    | 50 ± 23      |
| Dutch   | 48      | 98 ± 7       | 31      | 99 ± 2       | 71                    | 52 ± 20      |
| Italian | NA      | NA           | NA      | NA           | 50                    | 52 ± 18      |
| German  | 48      | 98 ± 7       | 31      | 99 ± 2       | 15                    | 73 ± 13      |
| Turkish | 55      | 97 ± 1       | NA      | NA           | 52                    | 53 ± 14      |
| Danish  | 75      | 93 ± 12      | NA      | NA           | 71                    | 51 ± 19      |
| French  | 22      | 99 ± 1       | 63      | 94 ± 7       | 31                    | 59 ± 18      |
| Spanish | 70      | 98 ± 2       | 70      | 93 ± 6       | 70                    | 54 ± 13      |

Abbreviations: NA, not available; VISA-A, Victorian Institute of Sport Assessment-Achilles.

\*Values are mean ± SD points unless otherwise indicated.

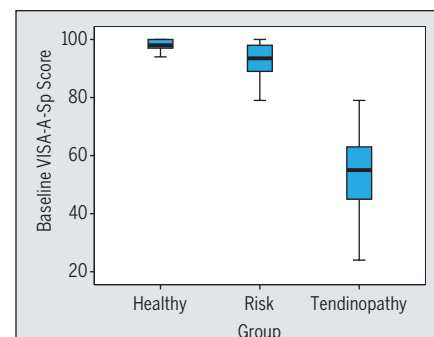


FIGURE 3. Mean scores on the VISA-A, with standard deviations. Differences between the healthy group and the pathology groups are shown. Abbreviations: Sp, Spanish; VISA-A, Victorian Institute of Sport Assessment-Achilles.

important difference (MCID), defined as the smallest change that is meaningful to the patient for an outcome measure, expressed in the same units as those of the questionnaire.<sup>13</sup> Tumilty et al<sup>43</sup> suggested that the MCID of the VISA-A questionnaire ranges from 12 to 20 points. However, McCormack et al<sup>34</sup> reported an MCID of 6.5 points. The selected sample size and the interpretation of a relevant change in the external anchor used in these studies are factors that could affect the results of the MCID estimation.<sup>13</sup> In addition, to avoid error measurement and to assess a clinical change, it is essential that the MCID value be higher than the MDC.<sup>43</sup> Norman et al<sup>36</sup> found that the value of 0.5 SD corresponds to the threshold of the MCID. Considering this premise, for our study, the threshold would be 6.5, which would agree with Iversen et al.<sup>22</sup> But given the highest SD reported for the VISA-A scores within patient groups in other studies, the threshold would be 11 points. Wyrwich<sup>44</sup> reported that the MCID in musculoskeletal disorders could be 2.3 or 2.6 times the SEM. Considering our data, with a SEM of 2.53, the MCID would be placed at 6.6 points.

Nevertheless, we are considering the minimum relevant change; although it is an important threshold, it does not generally represent a desirable treatment outcome for all patients.<sup>38</sup> The most clinically relevant changes from the patient's perspective correspond with greater magnitude changes in score, which are closer to the values of substantial clinical benefit.<sup>18</sup> In this sense, the expert panel consensus of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials concluded that a 30% improvement in scores, relative to baseline, may be considered a clinically meaningful improvement when using a patient-reported outcome.<sup>15</sup> Considering this threshold, the MCID value in our sample would be 16 points, as stated by Tumilty et al.<sup>43</sup>

Therefore, it is important to determine the responsiveness and the MCID

of the VISA-A in future studies associated with self-rated improvements in order to increase its clinical applicability and its value for clinical decision making.<sup>13,38</sup>

For example, in the return-to-sport program for patients with Achilles tendinopathy proposed by Silbernagel and Crossley,<sup>40</sup> the presence of pain/symptoms is integrated into the program for proper management of the individual. This is an example in which the use of the VISA-A questionnaire can help in clinical decision making and management. In fact, the Futbol Club Barcelona medical staff, in their guide to clinical practice for tendinopathies, specifically incorporate changes in the VISA-A score into the criteria to determine return-to-play status in players with Achilles tendinopathy.<sup>17</sup>

Finally, some limitations of the current study should be recognized. First, we did not include subjects treated surgically, as in the study developing the original version. As Maffulli et al<sup>32</sup> reported, current development in nonsurgical therapies has drastically reduced the number of athletes who receive surgical treatment for Achilles tendinopathy. Second, we have reported only distribution-based parameters for responsiveness, but these parameters do not provide information about clinical relevance. It could be interesting in future studies to estimate thresholds such as MCID. Third, there were fewer women in the healthy group than men. It would be interesting to analyze sex differences in future studies. Further, the Achilles tendinopathy group was older compared to the other 2 groups, so it would be interesting to explore results in younger subjects (eg, adolescents) with Achilles tendinopathy.

## CONCLUSION

**T**HE SPANISH VERSION OF THE VISA-A questionnaire has demonstrated adequate reliability and validity. After the cross-cultural adaptation pro-

cess, its psychometric properties are consistent with those of the original version. Further, the Spanish version is user friendly and can be easily self-administered. Therefore, the Spanish version of the VISA-A can be used as the main outcome by clinicians and researchers in Spanish-speaking athletes with Achilles tendinopathy for monitoring symptom course during treatment. ●

## KEY POINTS

**FINDINGS:** The Spanish version of the Victorian Institute of Sport Assessment-Achilles (VISA-A-Sp) questionnaire is a valid and reliable instrument to assess the severity of symptoms in athletes with Achilles tendinopathy. The VISA-A-Sp is comparable to the original version and other published international versions of the questionnaire.

**IMPLICATIONS:** The VISA-A-Sp questionnaire can be used as an outcome measure to assess Spanish-speaking athletes with Achilles tendinopathy and to monitor their symptoms after treatment.

**CAUTION:** Further research is necessary to determine the internal structure of the Victorian Institute of Sport Assessment-Achilles questionnaire and, prospectively, its minimum clinically important difference thresholds.

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# [ RESEARCH REPORT ]

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# [ RESEARCH REPORT ]

## APPENDIX

### Cuestionario VISA-A para la valoración de la severidad clínica de la tendinopatía Aquilea

NOMBRE Y APELLIDOS: ..... FECHA: .../.../.....

En este cuestionario, el término dolor se refiere específicamente a la región del tendón de Aquiles. Para indicar su intensidad de dolor, por favor, marque de 0 a 10 en la escala de respuesta teniendo en cuenta que **0 = ausencia de dolor y 10 = máximo dolor que imagina.**

1. ¿Durante cuántos minutos siente rigidez en la zona del tendón al levantarse por la mañana?

0 minutos

|       |        |        |        |        |        |        |        |        |        |         |
|-------|--------|--------|--------|--------|--------|--------|--------|--------|--------|---------|
| 0 min | 10 min | 20 min | 30 min | 40 min | 50 min | 60 min | 70 min | 80 min | 90 min | 100 min |
| 10    | 9      | 8      | 7      | 6      | 5      | 4      | 3      | 2      | 1      | 0       |

100 minutos

PUNTOS

2. Una vez que ha entrado en calor, ¿siente dolor al estirar completamente el tendón de Aquiles en el borde de un escalón (sobre las puntas de los pies y con la rodilla extendida, como en la imagen)?



PUNTOS

Sin dolor

|    |   |   |   |   |   |   |   |   |   |    |
|----|---|---|---|---|---|---|---|---|---|----|
| 0  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0  |

Dolor muy intenso

3.- Después de caminar 30 minutos en llano, ¿siente dolor en el tendón en las dos horas siguientes?

*Si no es capaz de andar durante 30 minutos en terreno llano, puntúe 0 en esta pregunta.*

PUNTOS

Sin dolor

|    |   |   |   |   |   |   |   |   |   |    |
|----|---|---|---|---|---|---|---|---|---|----|
| 0  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0  |

Dolor muy intenso

4.- ¿Le duele al bajar escaleras a un paso normal?

PUNTOS

Sin dolor

|    |   |   |   |   |   |   |   |   |   |    |
|----|---|---|---|---|---|---|---|---|---|----|
| 0  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0  |

Dolor muy intenso

5.- ¿Le duele el tendón cuando se pone de puntillas 10 veces sobre la misma pierna en una superficie plana o inmediatamente después de hacerlo?

PUNTOS

Sin dolor

|    |   |   |   |   |   |   |   |   |   |    |
|----|---|---|---|---|---|---|---|---|---|----|
| 0  | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0  |

Dolor muy intenso

6.- ¿Cuántos saltos puede hacer sobre una sola pierna sin dolor en la zona del tendón?

PUNTOS

|   |   |   |   |   |   |   |   |   |   |    |
|---|---|---|---|---|---|---|---|---|---|----|
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

CONTINÚA DETRÁS ➞

## APPENDIX

### Cuestionario VISA-A para la valoración de la severidad clínica de la tendinopatía Aquilea

#### 7.- ¿Practica actualmente algún deporte u otra actividad física?

- 0 ☐ No, en absoluto  
 4 ☐ Entrenamiento y/o competición modificada  
 7 ☐ Entrenamiento y/o competición completa, pero no al mismo nivel que cuando empezaron los síntomas  
 10 ☐ Competición al mismo nivel o superior al que tenía cuando empezaron los síntomas

PUNTOS

#### 8.- Por favor, lea los siguientes apartados y conteste A, B o C en esta pregunta según el estado actual de su lesión:

- Si no tiene dolor al realizar deportes que carguen (soliciten) el tendón de Aquiles, por favor, complete solamente la pregunta 8a
- Si tiene dolor mientras practica deportes de carga sobre el tendón de Aquiles pero éste no le impide finalizar la actividad, por favor, conteste solamente la cuestión 8b.
- Si tiene un dolor que le impide completar deportes que solicitan el tendón de Aquiles, por favor, complete únicamente la pregunta 8c.

#### 8a. Si no tiene dolor al realizar deportes que carguen el tendón de Aquiles ¿durante cuanto tiempo puede entrenar/practicar esos deportes?

|      |              |               |               |              |
|------|--------------|---------------|---------------|--------------|
| 0    | 7            | 14            | 21            | 30           |
| Nada | 1-10 minutos | 11-20 minutos | 21-30 minutos | > 30 minutos |

PUNTOS

#### 8b. Si tiene algo de dolor mientras practica deportes que carguen el tendón de Aquiles, pero no le impide completar su entrenamiento/práctica deportiva, ¿durante cuanto tiempo puede entrenar/practicar esos deportes?

|      |              |               |               |              |
|------|--------------|---------------|---------------|--------------|
| 0    | 4            | 10            | 14            | 20           |
| Nada | 1-10 minutos | 11-20 minutos | 21-30 minutos | > 30 minutos |

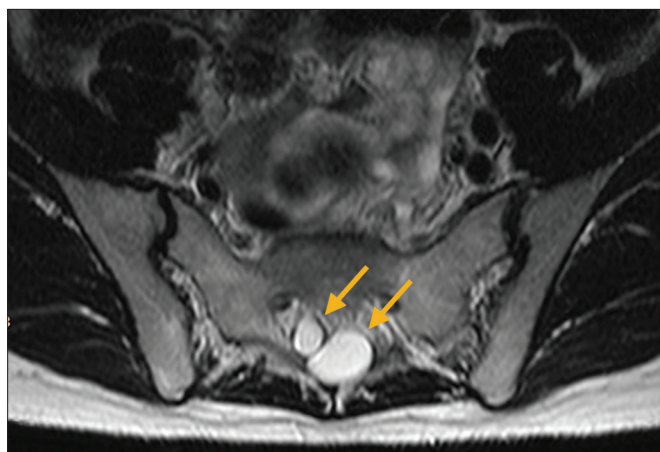
PUNTOS

#### 8c. Si tiene un dolor que le impide completar entrenamientos o deportes que carguen el tendón de Aquiles, ¿durante cuánto tiempo puede entrenar o practicar esos deportes?

|      |              |               |               |              |
|------|--------------|---------------|---------------|--------------|
| 0    | 2            | 5             | 7             | 10           |
| Nada | 1-10 minutos | 11-20 minutos | 21-30 minutos | > 30 minutos |

PUNTOS

PUNTUACIÓN TOTAL: ( /100)



**FIGURE 1.** Axial T2-weighted magnetic resonance imaging of the lumbosacral spine revealing perineural (Tarlov) cysts (arrows) at the level of S2.



**FIGURE 2.** Sagittal T2-weighted magnetic resonance imaging of the lumbosacral spine revealing perineural (Tarlov) cysts (arrows) at the levels of S2 and S3.

## Tarlov Cysts in a Woman With Lumbar Pain

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**A** 25-YEAR-OLD WOMAN PRESENTED to her primary care physician with thoracic spine pain. The pain started after lifting weights and resolved with muscle relaxants, heat, and ice. Two weeks later, the patient returned to her primary care physician with lumbar spine pain that limited her gym exercise and sitting for 30 minutes or less. She also reported an instantaneous episode of nonspecific tingling in her right posterior thigh. She reported no prior episodes of paresthesia, weakness, incoordination, or bowel/bladder dysfunction. The patient's physician prescribed oral corticosteroids and referred her to physical therapy.

The physical therapist's examination revealed mild hip weakness, limited active lumbar motion (all planes), and painful hypomobile L4-S1 spinal

segments without symptom peripheralization. Hip, sacroiliac joint, and neurological examinations were non-contributory. Pain decreased with spine mobilization. She was prescribed prone lumbar extension mobilization and general hip strengthening.

At the next visit 1 week later, the patient reported decreased back pain, but also reported an episode of nonspecific paresthesia into both legs and genitalia. Neurological re-examination was again unremarkable; however, she was instructed to abstain from exercises and referred to her primary care physician, as vague bilateral paresthesia complaints raised concern for a mass or other source of neurologic compression.

Magnetic resonance imaging revealed 4 sacral perineural (Tarlov) cysts (FIGURES 1 and 2). Tarlov cysts are benign cerebrospi-

nal fluid-filled meningeal dilations of the posterior spinal nerve root sheath, found most commonly in sacral roots.<sup>2,3</sup> While they occur in up to 5% of the population, only 1% cause pain or neurological symptoms.<sup>1</sup> After neurosurgery consultation, no surgical intervention was recommended. Nonsurgical management with medication and physical therapy is often recommended, because surgical procedures have resulted in inconsistent outcomes.<sup>1</sup>

After 2 months of nonsurgical management, the patient's back pain resolved and her neurogenic symptoms decreased in frequency, allowing for unlimited sitting and exercise. Tarlov cysts found on imaging may be concerning but are indeterminate as a contributor to symptoms. ● *J Orthop Sports Phys Ther* 2018;48(2):121. doi:10.2519/jospt.2018.7644

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# CLINICAL PRACTICE GUIDELINES

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## Knee Pain and Mobility Impairments: Meniscal and Articular Cartilage Lesions Revision 2018

*Clinical Practice Guidelines Linked to the  
International Classification of Functioning,  
Disability and Health From the Orthopaedic Section  
of the American Physical Therapy Association*

*J Orthop Sports Phys Ther.* 2018;48(2):A1-A50. doi:10.2519/jospt.2018.0301

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For author, coordinator, contributor, and reviewer affiliations, see end of text. ©2018 Orthopaedic Section, American Physical Therapy Association (APTA), Inc, and the *Journal of Orthopaedic & Sports Physical Therapy*. The Orthopaedic Section, APTA, Inc, and the *Journal of Orthopaedic & Sports Physical Therapy* consent to the reproduction and distribution of this guideline for educational purposes. Address correspondence to Brenda Johnson, ICF-Based Clinical Practice Guidelines Coordinator, Orthopaedic Section, APTA, Inc, 2920 East Avenue South, Suite 200, La Crosse, WI 54601. E-mail: icf@orthopt.org

## Summary of Recommendations<sup>\*†</sup>

### EXAMINATION – OUTCOME MEASURES: ACTIVITY LIMITATIONS/SELF-REPORTED MEASURES

#### 2018 Recommendation

**B** For knee-specific outcomes, clinicians should use the International Knee Documentation Committee 2000 Subjective Knee Evaluation Form (IKDC 2000) or Knee injury and Osteoarthritis Outcome Score (KOOS) (or a culturally appropriate version for patients whose primary language is not English) and may use the Lysholm scale (with removal of swelling item, and using unweighted scores).

**C** Clinicians may use the Tegner scale or Marx activity rating scale to assess activity level before and after interventions intended to alleviate the physical impairments, activity limitations, and participation restrictions associated with meniscus or articular cartilage lesions; however, these have less evidence support about measurement properties. The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) or the European Quality of Life-5 Dimensions (EQ-5D) are appropriate general health measures in this population. The Knee Quality of Life 26-item questionnaire (KQoL-26) may be used to assess knee-related quality of life.

### EXAMINATION – PHYSICAL PERFORMANCE MEASURES

#### 2018 Recommendation

**C** Clinicians may administer appropriate clinical or field tests, such as single-legged hop tests (eg, single hop for distance, cross-over hop for distance, triple hop for distance, and 6-m timed hop), that can identify a patient's baseline status relative to pain, function, and disability; detect side-to-side asymmetries; assess global knee function; determine a patient's readiness to return to activities; and monitor changes in the patient's status throughout the course of treatment.

### EXAMINATION – PHYSICAL IMPAIRMENT MEASURES

#### 2018 Recommendation

**B** Clinicians should administer appropriate physical impairment assessments of body structure and function, at least at baseline and at discharge or 1 other follow-up point, for all patients with meniscus tears to support standardization for quality improvement in clinical care and research, including the modified stroke test for effusion assessment, assessment of knee active range of motion, maximum voluntary isometric or isokinetic quadriceps strength testing, forced hyperextension, maximum passive knee flexion, McMurray's maneuver, and palpation for joint-line tenderness.

**D** Clinicians may administer the appropriate physical impairment assessments of body structure and function, at least at baseline and at discharge or 1 other follow-up point, for all patients with articular cartilage lesions to support standardization for quality improvement in clinical care and research, including the modified stroke test for effusion assessment, assessment of knee active range of motion, maximum voluntary isometric or isokinetic quadriceps strength testing, and palpation for joint-line tenderness.

### INTERVENTIONS – PROGRESSIVE KNEE MOTION

#### 2018 Recommendation

**B** Clinicians may use early progressive active and passive knee motion with patients after knee meniscal and articular cartilage surgery.

### INTERVENTIONS – PROGRESSIVE WEIGHT BEARING

#### 2018 Recommendation

**C** Clinicians may consider early progressive weight bearing in patients with meniscal repairs.

**B** Clinicians should use a stepwise progression of weight bearing to reach full weight bearing by 6 to 8 weeks after matrix-supported autologous chondrocyte implantation (MACI) for articular cartilage lesions.

### INTERVENTIONS – PROGRESSIVE RETURN TO ACTIVITY

#### 2018 Recommendation

**C** Clinicians may utilize early progressive return to activity following knee meniscal repair surgery.

**E** Clinicians may need to delay return to activity depending on the type of articular cartilage surgery.

### INTERVENTIONS – SUPERVISED REHABILITATION

#### 2018 Recommendation

**B** Clinicians should use exercises as part of the in-clinic supervised rehabilitation program after arthroscopic meniscectomy and should provide and supervise the progression of a home-based exercise program, providing education to ensure independent performance.

### INTERVENTIONS – THERAPEUTIC EXERCISES

#### 2018 Recommendation

**B** Clinicians should provide supervised, progressive range-of-motion exercises, progressive strength training of the knee and hip muscles, and neuromuscular training to patients with knee meniscus tears and articular cartilage lesions and after meniscus or articular cartilage surgery.

### INTERVENTIONS – NEUROMUSCULAR ELECTRICAL STIMULATION/BIOFEEDBACK

#### 2018 Recommendation

**B** Clinicians should provide neuromuscular stimulation/re-education to patients following meniscus procedures to increase quadriceps strength, functional performance, and knee function.

<sup>\*</sup>As per the original guidelines, these revised guidelines are primarily aimed at the diagnosis, evaluation, assessment, and treatment interventions of meniscal and articular cartilage lesions with respect to postsurgical care.

<sup>†</sup>These recommendations and clinical practice guidelines are based on the scientific literature published prior to December 2016.

## List of Abbreviations

**ACI:** autologous chondrocyte implantation

**ACL:** anterior cruciate ligament

**AE:** athlete exposure

**AGREE:** Appraisal of Guidelines for Research and Evaluation

**AMIC:** autologous matrix-induced chondrogenesis

**APM:** arthroscopic partial meniscectomy

**APTA:** American Physical Therapy Association

**CI:** confidence interval

**CPG:** clinical practice guideline

**EQ-5D:** European Quality of Life-5 Dimensions

**HCQ:** Hughston Clinic Questionnaire

**ICC:** intraclass correlation coefficient

**ICD:** International Classification of Diseases

**ICF:** International Classification of Functioning, Disability and Health

**ICRS:** International Cartilage Repair Society

**IKDC 2000:** International Knee Documentation Committee 2000 Subjective Knee Evaluation Form

**JOSPT:** *Journal of Orthopaedic & Sports Physical Therapy*

**KOOS:** Knee injury and Osteoarthritis Outcome Score

**KQoL-26:** Knee Quality of Life 26-item questionnaire

**MACI:** matrix-supported autologous chondrocyte implantation

**MCID:** minimal clinically important difference

**MCMI:** medial collagen meniscus implant

**MRI:** magnetic resonance imaging

**OAT:** osteochondral autograft transplantation

**OCT:** osteochondral transfer

**OR:** odds ratio

**RCT:** randomized controlled trial

**SF-36:** Medical Outcomes Study 36-Item Short-Form Health Survey

**SF-6D:** Medical Outcomes Study Short Form-6 Dimensions

**SMD:** standardized mean difference

**VAS:** visual analog scale

**WOMAC:** Western Ontario and McMaster Universities Osteoarthritis Index

**WOMET:** Western Ontario Meniscal Evaluation Tool

## Introduction

### AIM OF THE GUIDELINES

The Orthopaedic Section of the American Physical Therapy Association (APTA) supports an ongoing initiative to create evidence-based clinical practice guidelines (CPGs) for orthopaedic physical therapy management of patients with musculoskeletal impairments described in the World Health Organization's International Classification of Functioning, Disability and Health (ICF).<sup>142</sup>

The purposes of these clinical guidelines are to:

- Describe evidence-based physical therapy practice, including diagnosis, prognosis, intervention, and assessment of outcome for musculoskeletal disorders commonly managed by orthopaedic physical therapists
- Classify and define common musculoskeletal conditions using the World Health Organization's terminology related to impairments of body function and body structure, activity limitations, and participation restrictions
- Identify interventions supported by current best evidence to address impairments of body function and structure, activity limitations, and participation restrictions associ-

ated with common musculoskeletal conditions

- Identify appropriate outcome measures to assess changes resulting from physical therapy interventions in body function and structure as well as in activity and participation of the individual
- Provide a description to policy makers, using internationally accepted terminology, of the practice of orthopaedic physical therapists
- Provide information for payers and claims reviewers regarding the practice of orthopaedic physical therapy for common musculoskeletal conditions
- Create a reference publication for orthopaedic physical therapy clinicians, academic instructors, clinical instructors, students, interns, residents, and fellows regarding the best current practice of orthopaedic physical therapy

### STATEMENT OF INTENT

These guidelines are not intended to be construed or to serve as a standard of medical care. Standards of care are determined on the basis of all clinical data available for an individual patient and are subject to change as scientific knowledge and technology advance and patterns of care evolve. These parameters of practice should be considered

## Introduction (*continued*)

guidelines only. Adherence to them will not ensure a successful outcome in every patient, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgment regarding a particular clinical procedure or treatment plan must be made based on clinician experience and expertise in light of the clinical presentation of the patient, the available evidence, available diagnostic and treatment options, and the patient's values, expectations, and preferences. However, we suggest that significant departures from accepted guidelines should be documented in the patient's medical records at the time the relevant clinical decision is made.

### SCOPE

The aims of the revision were to provide a concise summary of the evidence since publication of the original guideline in 2010 and to develop new recommendations or revise previously published recommendations to support evidence-based practice. The original guidelines were primarily aimed at the diagnosis, evaluation, assessment, and treatment interventions of meniscus and articular cartilage lesions with respect to postsurgical care, and this revision builds on the original guidelines. The state of the literature in the nonoperative management of meniscus and articular cartilage lesions is rapidly evolving and will be explored and presented in the next iteration of this CPG.

## Methods

Content experts with relevant physical therapy, medical, and surgical expertise were appointed by the Orthopaedic Section, APTA, Inc to conduct a review of the literature and to develop an updated Knee Pain and Mobility Impairments Meniscal and Articular Cartilage Lesions CPG as indicated by the current state of the evidence in the field. Four authors of this guideline revision completed the Appraisal of Guidelines for Research and Evaluation (AGREE) II tool to assess the quality and reporting of the CPG published in 2010, and to identify areas for improvement. The authors of this guideline revision worked with the CPG Editors and medical librarians for methodological guidance. The research librarians were chosen for their expertise in systematic review rehabilitation literature search, and to perform systematic searches for concepts associated with meniscus and articular cartilage injuries of the knee in articles published from 2008 related to classification, examination, and intervention strategies consistent with previous guideline development methods related to ICF classification.<sup>91</sup> Briefly, the following databases were searched from 2008 to December 31, 2016: MEDLINE (PubMed, 2008 to date), Scopus (Elsevier BV, 2008 to date), CINAHL (EBSCO, 2008 to date), SPORTDiscus (EBSCO, 2008 to date), and Cochrane Library (Wiley, 2008 to date). (See **APPENDIX A** for full search strategies and **APPENDIX B** for search dates and results, available at [www.orthopt.org](http://www.orthopt.org).)

The authors declared relationships and developed a conflict management plan that included submitting a Conflict of Interest form to the Orthopaedic Section, APTA, Inc. Articles that were authored by a reviewer were assigned to an alter-

nate reviewer. Funding was provided to the CPG development team for travel and expenses for CPG development training by the Orthopaedic Section, APTA, Inc. The CPG development team maintained editorial independence.

Articles contributing to recommendations were reviewed based on specified inclusion and exclusion criteria with the goal of identifying evidence relevant to physical therapist clinical decision making for adult persons with knee pain and mobility impairments/knee meniscal/articular cartilage lesions. The title and abstract of each article were reviewed independently by 2 members of the CPG development team for inclusion. (See **APPENDIX C** for inclusion and exclusion criteria, available at [www.orthopt.org](http://www.orthopt.org).) Full-text review was then similarly conducted to obtain the final set of articles for contribution to recommendations. The team leader (D.S.L.) provided the final decision for discrepancies that were not resolved by the review team. (See **APPENDIX D** for a flow chart of articles and **APPENDIX E** for articles included in recommendations by topic, available at [www.orthopt.org](http://www.orthopt.org).) For selected relevant topics that were not appropriate for the development of recommendations, such as incidence and imaging, articles were not subject to the systematic review process and were not included in the flow chart. Evidence tables for this CPG are available on the Clinical Practice Guidelines page of the Orthopaedic Section of the APTA website: [www.orthopt.org](http://www.orthopt.org).

This guideline was issued in 2018 based on the published literature up to December 2016, and will be considered for review in 2022, or sooner if new evidence becomes available that may change the recommendations. Any updates to the

## Methods (*continued*)

guideline in the interim period will be noted on the Orthopaedic Section of the APTA website: [www.orthopt.org](http://www.orthopt.org).

### LEVELS OF EVIDENCE

Individual clinical research articles were graded according to criteria adapted from the Centre for Evidence-Based Medicine, Oxford, United Kingdom for diagnostic, prospective, and therapeutic studies.<sup>114</sup> In 3 teams of 2, each reviewer independently assigned a level of evidence and evaluated the quality of each article using a critical appraisal tool. (See **APPENDICES F** and **G** for the Levels of Evidence table and details on procedures used for assigning levels of evidence, available at [www.orthopt.org](http://www.orthopt.org).) The evidence update was organized from highest level of evidence to lowest level. An abbreviated version of the grading system is provided below.

|            |                                                                                                                                                                                                                                                           |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>I</b>   | Evidence obtained from systematic reviews, high-quality diagnostic studies, prospective studies, or randomized controlled trials                                                                                                                          |
| <b>II</b>  | Evidence obtained from systematic reviews, lesser-quality diagnostic studies, prospective studies, or randomized controlled trials (eg, weaker diagnostic criteria and reference standards, improper randomization, no blinding, less than 80% follow-up) |
| <b>III</b> | Case-control studies or retrospective studies                                                                                                                                                                                                             |
| <b>IV</b>  | Case series                                                                                                                                                                                                                                               |
| <b>V</b>   | Expert opinion                                                                                                                                                                                                                                            |

### GRADES OF EVIDENCE

The strength of the evidence supporting the recommendations was graded according to the previously established methods for the original guideline and those provided below. Each team developed recommendations based on the strength of evidence, including how directly the studies addressed the question on knee pain and mobility impairments/meniscus and articular cartilage lesion population. In developing their recommendations, the authors considered the strengths and limitations of the body of evidence and the health benefits, side effects, and risks of tests and interventions.

| GRADES OF RECOMMENDATION BASED ON |                   | STRENGTH OF EVIDENCE                                                                                                                                     |
|-----------------------------------|-------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>A</b>                          | Strong evidence   | A preponderance of level I and/or level II studies support the recommendation. This must include at least 1 level I study                                |
| <b>B</b>                          | Moderate evidence | A single high-quality randomized controlled trial or a preponderance of level II studies support the recommendation                                      |
| <b>C</b>                          | Weak evidence     | A single level II study or a preponderance of level III and IV studies, including statements of consensus by content experts, support the recommendation |

| GRADES OF RECOMMENDATION BASED ON |                                   | STRENGTH OF EVIDENCE                                                                                                                                        |
|-----------------------------------|-----------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>D</b>                          | Conflicting evidence              | Higher-quality studies conducted on this topic disagree with respect to their conclusions. The recommendation is based on these conflicting studies         |
| <b>E</b>                          | Theoretical/foundational evidence | A preponderance of evidence from animal or cadaver studies, from conceptual models/principles, or from basic science/bench research support this conclusion |
| <b>F</b>                          | Expert opinion                    | Best practice based on the clinical experience of the guidelines development team                                                                           |

### DESCRIPTION OF GUIDELINE VALIDATION

Identified reviewers who are experts in knee meniscus and articular cartilage injury management and rehabilitation reviewed this CPG content and methods for integrity, accuracy, and that it fully represents the condition. All comments, suggestions, or feedback from the expert reviewers were delivered to the authors and editors to consider and make appropriate revisions. These guidelines were also posted for public comment and review on the [orthopt.org](http://orthopt.org) website and a notification of this posting was sent to the members of the Orthopaedic Section, APTA, Inc. All comments, suggestions, and feedback gathered from public commentary were sent to the authors and editors to consider and make appropriate revisions in the guideline. In addition, a panel of consumer/patient representatives and external stakeholders, such as claims reviewers, medical coding experts, academic educators, clinical educators, physician specialists, and researchers, also reviewed the guideline and provided feedback and recommendations that were given to the authors and editors for further consideration and revisions. Last, a panel of consumer/patient representatives and external stakeholders and a panel of experts in physical therapy practice guideline methodology annually review the Orthopaedic Section, APTA's ICF-based Clinical Practice Guideline policies and provide feedback and comments to the Clinical Practice Guidelines Coordinator and Editors to improve the Association's guideline development and implementation processes.

### DISSEMINATION AND IMPLEMENTATION TOOLS

In addition to publishing these guidelines in the *Journal of Orthopaedic & Sports Physical Therapy (JOSPT)*, these guidelines will be posted on CPG areas of both the *JOSPT* and the Orthopaedic Section, APTA websites, which are free-access website areas, and submitted to be available free access on the Agency for Healthcare Research and Quality's website ([www.guideline.gov](http://www.guideline.gov)). The implementation tools planned to be available for patients, clinicians, educators, payers, policy

## Methods *(continued)*

makers, and researchers, and the associated implementation strategies, are listed in the **TABLE**.

### CLASSIFICATION

The International Classification of Diseases-10 (ICD-10) codes and conditions associated with knee pain and mobility disorders are **S83.2 Tear of meniscus, current**; **M23.2 Derangement of meniscus due to old tear or injury**; and **S83.3 Tear of articular cartilage of knee, current**.

The corresponding ICD-9 Clinical Modification (CM) codes and conditions, which are used in the United States, associated with knee pain and mobility disorders are **836.0 Tear of medial cartilage or meniscus of knee, current**; **836.1 Tear of lateral cartilage or meniscus of knee, current**; **717.0 Old bucket handle tear of medial meniscus**; **717.1 Derangement of anterior horn of medial meniscus**; **717.2 Derangement of posterior horn of medial meniscus**; **717.3 Other and unspecified derangement of medial meniscus**; **717.40 Derangement of lateral meniscus unspecified**; **717.41 Bucket handle tear of lateral meniscus**; **717.42 Derangement of anterior horn of lateral meniscus**; **717.43 Derangement of posterior horn of lateral meniscus**; **717.49 Other derangement of lateral meniscus**; and **717.89 Other internal derangement of knee**.

The primary ICF body functions codes associated with the above-noted ICD-10 conditions are **b28016 Pain in joints**; **b7100 Mobility of a single joint**; and **b770 Gait pattern functions**.

The primary ICF body structures codes associated with knee pain and mobility disorders are **s75000 Bones of thigh**, **s75010 Bones of lower leg**; **s75011 Knee joint**; and **s75018 Structure of lower leg, specified as fibrocartilage or hyaline cartilage of the knee**.

The primary ICF activities and participation codes associated with knee pain and mobility disorders are **d2302 Completing the daily routine** and **d4558 Moving around, specified as quick direction changes while walking or running**.

A comprehensive list of codes was published in the previous guideline.<sup>91</sup>

### ORGANIZATION OF THE GUIDELINE

For each topic, the summary recommendation and grade of evidence from the 2010 guideline are presented, followed by a synthesis of the recent literature with the corresponding evidence levels. Each topic concludes with the 2018 summary recommendation and its updated grade of evidence.

## TABLE

### PLANNED STRATEGIES AND TOOLS TO SUPPORT THE DISSEMINATION AND IMPLEMENTATION OF THIS CLINICAL PRACTICE GUIDELINE

| Tool                                                                                       | Strategy                                                                                                                                                                                      |
|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| "Perspectives for Patients"                                                                | Patient-oriented guideline summary available on <a href="http://www.jospt.org">www.jospt.org</a> and <a href="http://www.orthopt.org">www.orthopt.org</a>                                     |
| Mobile app of guideline-based exercises for patients/clients and health care practitioners | Marketing and distribution of app using <a href="http://www.orthopt.org">www.orthopt.org</a> and <a href="http://www.jospt.org">www.jospt.org</a>                                             |
| Clinician's quick-reference guide                                                          | Summary of guideline recommendations available on <a href="http://www.orthopt.org">www.orthopt.org</a>                                                                                        |
| Read-for-credit continuing education units                                                 | Continuing education units available for physical therapists and athletic trainers through <i>JOSPT</i>                                                                                       |
| Educational webinars for health care practitioners                                         | Guideline-based instruction available for practitioners on <a href="http://www.orthopt.org">www.orthopt.org</a>                                                                               |
| Mobile and web-based app of guideline for training of health care practitioners            | Marketing and distribution of app using <a href="http://www.orthopt.org">www.orthopt.org</a> and <a href="http://www.jospt.org">www.jospt.org</a>                                             |
| Physical Therapy National Outcomes Data Registry                                           | Support the ongoing usage of data registry for common musculoskeletal conditions of the head and neck region                                                                                  |
| Logical Observation Identifiers Names and Codes mapping                                    | Publication of minimal data sets and their corresponding Logical Observation Identifiers Names and Codes for the head and neck region on <a href="http://www.orthopt.org">www.orthopt.org</a> |
| Non-English versions of the guidelines and guideline implementation tools                  | Development and distribution of translated guidelines and tools to <i>JOSPT</i> 's international partners and global audience via <a href="http://www.jospt.org">www.jospt.org</a>            |

## CLINICAL GUIDELINES

# Impairment/Function-Based Diagnosis

## INCIDENCE

### 2010 Summary

#### Meniscus

Injuries to the menisci are the second most common injury to the knee, with a prevalence of 12% to 14% and an incidence of 61 cases per 100 000 persons.<sup>96,128</sup> A high incidence of meniscal tears occur with injury to the anterior cruciate ligament (ACL), ranging from 22% to 86%.<sup>105</sup> In the United States, 10% to 20% of all orthopaedic surgeries consist of surgery to the meniscus on an estimated 850 000 patients each year.<sup>117</sup>

#### Articular Cartilage

Based on studies of knee arthroscopies, the prevalence of articular cartilage pathologies is reported to be between 60% and 70%.<sup>8,69</sup> The incidence of isolated articular cartilage lesions (30%) is lower than that of nonisolated cartilage lesions.<sup>139</sup> Thirty-two percent to 58% of all articular cartilage lesions are the result of a traumatic, noncontact mechanism of injury.<sup>74,139</sup> Sixty-four percent of all chondral lesions were less than 1 cm<sup>2</sup>.<sup>139</sup> Thirty-three percent to 60% of articular cartilage lesions are greater than grade 3 lesions on the International Cartilage Repair Society (ICRS) grading system.<sup>36,130</sup> The ICRS cartilage injury classification consists of 5 grading levels, from grade 0 (normal cartilage without notable defects) to grade 4 (severely abnormal, full-thickness osteochondral injury).<sup>21</sup> The most frequent localizations of cartilage lesions were to the medial femoral condyle and the patellar articular surface.<sup>139</sup> Medial meniscal tears (37%) and ACL ruptures (36%) were the most common injuries concomitant with articular cartilage injuries.

## Evidence Update

#### Meniscus

Tear patterns of the knee meniscus can be classified as either traumatic tears or degenerative tears.<sup>46</sup> Younger active participants are more likely to sustain traumatic meniscus injuries, such as longitudinal or radial tears. Older individuals are more likely to have degenerative tears, such as horizontal cleavages, flap or complex tears, or meniscal maceration or destruction.<sup>46</sup>

## II

In active-duty US military service personnel, Jones et al<sup>75</sup> reported an unadjusted incidence rate of 8.27 per 1000 person-years (95% CI: 8.22, 8.32) for

acute meniscal injury. For men, the adjusted rate per 1000 person-years was 7.08 and for women was 6.02. Oldest service personnel (older than 40 years of age) had more than 4 times (4.25) the adjusted rate of meniscus tears compared to youngest (less than 20 years of age) service personnel.

## III

Yeh et al<sup>146</sup> identified 129 isolated meniscus tears over a 21-season span in 1797 professional basketball players. One hundred eleven injuries (86.7%) were the result of a single incident. Lateral meniscus tears were involved in 59.2% and medial meniscus tears were involved in 40.8% of cases. Isolated tears accounted for 87.8% of cases, whereas 12.2% of cases were concomitant with a ligamentous injury. They reported an overall clinical incidence of 8.2 meniscus tears per 100 athletes. Lateral meniscus tears were more likely to occur in younger athletes (younger than or equal to 30 years of age), whereas medial meniscus tears were more prevalent in athletes older than 30 years of age.

## IV

In an injury surveillance study of high school athletes, the meniscus was involved in 23.0% of all knee injuries in all reported sports, corresponding to 0.51 injuries per 10 000 athlete exposures (AEs).<sup>129</sup> In sex-comparable sports, boys had 0.22 injuries per 10 000 AEs and girls had 0.42 injuries per 10 000 AEs, resulting in girls having a higher rate of meniscus injuries compared to boys (rate ratio = 1.88; 95% CI: 1.48, 2.40).

## IV

In a claims analysis study, Abrams et al<sup>1</sup> reported that from 2005 to 2011, 387 833 meniscectomies and 23 640 meniscus repairs were performed in the United States. The majority of meniscectomies performed were in the 45-to-54-year-old and 55-to-64-year-old age groups (32.9% and 32.2%, respectively, in 2011), whereas the majority of meniscal repairs were performed in the under-25-year-old and 25-to-34-year-old age groups (55.2% and 19.5%, respectively, in 2011). The authors reported only a small increase in the number of yearly meniscectomies from 2005 to 2011 (4.7%), but there was a larger increase (11.4%) in the number of yearly meniscus repairs. The overall incidence of meniscectomies went from 0.21% per year to 0.24% per year, whereas the incidence of meniscal repairs went from 0.01% per year to 0.02% per year.

IV

Similarly, in Denmark from 2000 to 2011, the number of yearly meniscus procedures doubled from 8750 to 17 368.<sup>134</sup> The largest increases in incidence rate in the same time period were seen in patients older than 55 years (3-fold increase) and in patients between 35 and 55 years of age (2-fold increase).

### Articular Cartilage

II

A systematic review of 11 studies (931 participants) looking at the prevalence of chondral lesions in athletes' knees identified by arthroscopy or magnetic resonance imaging (MRI) found that the overall prevalence of full-thickness focal chondral lesions was 36% (range, 2.4%-75%).<sup>51</sup> Thirty-five percent of lesions were located in the femoral condyles, 37% in the patella and trochlea, and 25% in the tibial plateaus. The prevalence of full-thickness focal chondral lesions in asymptomatic individuals was 14%, but was substantially higher in basketball players and endurance runners (59%; range, 18%-63%).

II

Brophy et al<sup>22</sup> examined 725 participants with revision ACL reconstructions to determine the presence of chondral lesions and their relationship with prior meniscus surgery. After adjusting for patient age, knees with prior partial meniscectomy were more likely to have cartilage deterioration compared to knees with prior meniscus repair or no previous history of meniscus surgery.

IV

Nepple et al<sup>103</sup> identified 432 articular cartilage abnormalities in 704 knee MRI scans from 594 participants from the National Football League Scouting Combine. Full-thickness lesions were present in 17% of knees, with the lateral compartment being the most common site. Previous surgery to the knee was significantly associated with full-thickness articular cartilage lesions.

IV

In a retrospective review, Ralles et al<sup>115</sup> reported that a delay in ACL reconstruction (greater than 12 months from the index injury) was associated with an increased incidence of medial meniscus lesions and cartilage lesions. Additionally, less active patients (based on Marx activity rating scale less than 7) were more likely to have cartilage lesions and medial meniscus tears compared to those who were more active.

### Meniscus and Articular Cartilage

III

Wyatt et al<sup>144</sup> investigated the prevalence of meniscus and cartilage lesions in a sample of 261 patients who had primary and subsequent revision ACL reconstruction. The prevalence of cartilage injuries was twice as common among those undergoing revision ACL reconstruction (31.8%) compared to those undergoing primary ACL reconstruction (14.9%). There was a higher prevalence

of meniscus tears at primary ACL reconstruction (54.8%) compared to revision ACL reconstruction (43.7%). There was a higher prevalence of lateral meniscus tears at primary ACL reconstruction (37.2%) compared to revision ACL reconstruction (18.4%), but no difference in prevalence of medial meniscus tears between primary (32.6%) and revision reconstruction (32.6%).

IV

Kuikka et al<sup>87</sup> reported on population-based incidence in young military men. They reported an incidence of 3.1 per 1000 person-years (95% CI: 2.7, 3.4) for old meniscus tears, 2.2 per 1000 person-years (95% CI: 1.9, 2.5) for new meniscus tears, and 0.2 per 1000 person-years (95% CI: 0.1, 0.3) for fresh chondral lesions. Twenty-seven percent of individuals were hospitalized for old meniscus tears, 19.9% for new meniscus tears, and 1.7% for chondral lesions. They reported that one third of service class changes were the result of meniscal tears and new chondral lesions.

### 2018 Summary

Meniscus lesions account for almost one quarter of all knee injuries. In high school athletes, girls may have higher incidence of meniscus tears than boys. Older individuals have a higher rate of meniscus tears compared to younger individuals. Lateral meniscus tears are more likely to occur in younger athletes, and medial meniscus tears are more likely to occur in older people. A high prevalence of meniscus tears are present in individuals undergoing primary and revision ACL reconstruction. Individuals older than 45 years of age are more likely to have meniscectomy, whereas individuals younger than 35 years of age are more likely to have meniscus repair. The incidence rate of meniscus procedures (partial meniscectomies and meniscus repairs) has substantially increased over the past decade.

The prevalence of articular cartilage lesions in athletes' knees ranges from 17% to 59%, some of those athletes being asymptomatic. The incidence rate of articular cartilage lesions is high after partial meniscectomy or second ACL injury.

## PATHOANATOMICAL FEATURES

### 2010 Summary

#### Meniscus

The medial and lateral menisci cover the superior aspect of the tibia.<sup>20</sup> Each meniscus is composed of fibrocartilage and is wedge shaped. The lateral meniscus is more circular, whereas the medial meniscus is more crescent shaped. The lateral meniscus is more mobile than the medial meniscus. The menisci function to distribute stress across the knee during weight bearing, provide shock absorption, serve as secondary joint stabilizers, provide articular cartilage nutrition and lubrication, facilitate joint gliding, prevent hyperextension, and protect the

joint margins.<sup>20</sup> Individuals who sustain a meniscal tear report a similar history as an individual with an ACL tear, such as feeling a “pop” while suddenly changing direction with or without contact.<sup>20</sup> The rate of medial meniscal tears increases over time, whereas lateral meniscal tears do not.<sup>76,105,130</sup> Prolonged delays in ACL reconstruction are related to increased occurrence of meniscus injuries.<sup>105</sup>

### Articular Cartilage

The articular cartilage that covers the gliding surfaces of the knee joint is hyaline in nature.<sup>16,88</sup> Hyaline cartilage decreases the friction between gliding surfaces, withstands compression by acting as a shock absorber, and resists wear during normal situations.<sup>16,24</sup> Injuries to the articular cartilage can be the result of acute trauma or repetitive minor trauma.<sup>16,74,139</sup> Some individuals who sustain articular surface injury do not seek treatment. Many lesions are nonprogressive and remain asymptomatic, while some experts believe that even small asymptomatic lesions may increase in size and eventually become painful if left untreated.<sup>55</sup> Four methods of operative care that are most widely used are arthroscopic lavage and debridement, microfracture, autologous chondrocyte implantation (ACI), and osteochondral autograft transplantation (OAT).<sup>88</sup>

### Evidence Update

None.

### 2018 Summary

Partial meniscectomy is the primary surgical procedure used to treat meniscus tears. Microfracture procedures for articular cartilage lesions are largely used for young patients, are associated with good outcomes, and have been combined with an extrinsic matrix known as autologous matrix-induced chondrogenesis (AMIC).

## CLINICAL COURSE

### 2010 Recommendation

**C** Knee pain and mobility impairments associated with meniscal and articular cartilage tears can be the result of a contact or noncontact incident, which can result in damage to one or more structures. Clinicians should assess for impairments in range of motion, motor control, strength, and endurance of the limb associated with the identified meniscal or articular cartilage pathology or following meniscal or chondral surgery.

### Evidence Update

#### Meniscus

**I** A systematic review of arthroscopy surgery for degenerative meniscus tears reported minimal short-term improvement favoring arthroscopy

surgery compared to other treatments for pain that was then absent at 1 to 2 years.<sup>135</sup> Furthermore, harms, such as symptomatic deep venous thrombosis, pulmonary embolism, infection, and death, are associated with knee arthroscopy.<sup>135</sup>

**I** In a randomized controlled trial (RCT), Frobell et al<sup>52</sup> reported that the number of meniscus surgeries over a 5-year period after ACL injury was similar in those who had early ACL reconstruction (n = 29) and those who had initial rehabilitation with the option of later reconstruction (n = 32). However, the frequency of repeated meniscus surgery was lower in those who had early ACL reconstruction compared to those who had initial rehabilitation with the option of later reconstruction.

**I** Katz et al<sup>78</sup> randomized 351 patients with a meniscus tear and mild to moderate knee osteoarthritis into either APM and rehabilitation or rehabilitation only. Patients were followed up at 6 and 12 months, and results were similar for the 2 groups. In the intention-to-treat analysis (adjusted for study site), at 6 months, the mean Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) physical function score improved by 20.9 points for the surgical group and 18.5 points for the rehabilitation group. At 12 months, the mean scores improved by 23.5 and 22.8 points for the surgical and rehabilitation groups, respectively. Similar improvements in both groups were reported in Knee injury and Osteoarthritis Outcome Score (KOOS) pain subscale scores at both time points. At 6 months, 30% of the patients assigned to the rehabilitation group crossed over to the surgery group, whereas 5% of patients assigned to the surgery group chose not to undergo surgery.

**II** A systematic review of 367 participants from 7 studies (1 RCT and 6 retrospective observational trials) evaluated outcomes comparing meniscal repair to meniscectomy.<sup>145</sup> Patients post meniscus repair reported similar long-term International Knee Documentation Committee 2000 Subjective Knee Evaluation Form (IKDC 2000) scores, higher Lysholm scores (mean difference, 5.24), and less change in Tegner scores (median difference, -0.81) compared to patients post meniscectomy. Patients post meniscus repair had better self-reported knee function and less activity loss compared to those post meniscectomy. However, the length of follow-up after surgery and type of study design may have influenced the outcomes.

**II** Hall et al<sup>61</sup> performed a systematic review on knee extensor muscle strength in patients older than 29 years undergoing APM, reporting on 11 studies involving 596 individuals. Before APM surgery, patients with

meniscus tear had lower knee extensor strength compared to healthy controls or their noninjured limb, with a standardized mean difference (SMD) of  $-0.58$  (95% CI:  $-1.13, -0.04$ ). After surgery, the lower knee extensor muscle strength persisted for up to 4 years (1 week after surgery: SMD,  $-2.42$ ; 95% CI:  $-3.36, -1.48$ ; 3–4 weeks after surgery: SMD,  $-0.47$ ; 95% CI:  $-1.06, 0.12$ ; 12 weeks after surgery: SMD,  $-0.47$ ; 95% CI:  $-0.91, 0.02$ ; 6 months after surgery: SMD,  $-0.56$ ; 95% CI:  $-1.05, -0.07$ ; 2 years after surgery: SMD,  $-0.01$ ; 95% CI:  $-0.36, 0.35$ ; and 4 years after surgery: SMD,  $-0.56$ ; 95% CI:  $-1.20, 0.08$ ). They reported that the involved limb was 11% to 12% weaker than controls before APM and up to 4 years after APM (except for the 2-year time point after APM).

**II** A systematic review of 4 studies (prospective and cross-sectional) assessing quadriceps strength after APM reported large quadriceps strength deficits less than 1 month after surgery (Cohen's  $d = -1.01$  to  $-1.62$ ), small to large deficits 1 to 3 months after surgery ( $d = -0.40$  to  $-0.84$ ), small to large deficits 3 to 6 months after surgery ( $d = -0.40$  to  $-0.51$ ), and small deficits ( $d = -0.30$  to  $-0.37$ ) more than 6 months after surgery.<sup>97</sup>

**II** In patients with degenerative meniscus lesions, Østerås et al<sup>109</sup> randomized 17 patients to either specialized exercise therapy or APM. The exercise therapy group had similar to better adjusted differences in change from baseline to 3 months' follow-up compared to the APM group for visual analog scale (VAS) pain scores (exercise therapy,  $-1.1$ ; APM,  $-1.1$ ), total KOOS scores (exercise therapy,  $-10.7$ ; APM,  $-8.9$ ), Hospital Anxiety and Depression Scale scores (exercise therapy,  $-1.7$ ; APM,  $-0.7$ ), and quadriceps muscle strength with maximal external load using 5 repetitions (exercise therapy,  $10.5$ ; APM,  $4.1$ ).

**II** Al-Dadah et al<sup>3</sup> investigated proprioception and self-reported knee function preoperatively (baseline) and 3 months later (follow-up) in patients undergoing knee arthroscopy. At baseline, the group scheduled for APM ( $n = 50$ ) had impaired proprioception compared to healthy controls and the contralateral uninjured knee. At follow-up, despite improvements in perceived knee function according to Lysholm, Cincinnati, and IKDC 2000 scores compared to preoperative scores, the APM leg continued to demonstrate impaired proprioception compared to the normal contralateral knee and to healthy controls.

**II** Busija et al<sup>26</sup> assessed the change in Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) scores in patients undergoing 4 types of orthopaedic surgeries (APM, ACL reconstruction, total hip arthroplasty, and total knee arthroplasty). In 63 patients

(85%) who underwent APM and completed 3-month follow-up assessment, a large effect size (1.0) was observed for improvement in body pain and a moderate effect size (0.70) for the physical component summary of the SF-36.

**II** Fabricant et al<sup>48</sup> studied factors related to patient recovery 12 months following APM. There were 141 patients included at baseline (tested 2–6 weeks prior to surgery) and 126 (89%) completed the study. Pain and knee function were rated by the surgeon. Variables assessed to predict recovery rate included osteoarthritis severity (modified Outerbridge score), meniscal excision depth, involvement of both menisci, extent of tear, sex, age, body mass index, and time (preoperative and 1, 3, 8, 16, 24, and 48 weeks post surgery). Of the variables assessed, female sex and greater osteoarthritis severity were associated with slower rate of short- to intermediate-term pain recovery, functional recovery, and overall knee status.

**II** In this 10-year study, Zaffagnini et al<sup>147</sup> compared clinical and structural outcomes in patients receiving a medial collagen meniscus implant (MCMI) compared to patients undergoing APM. Thirty-three of the 36 patients returned for reassessment (92%), and results showed that on average, patients receiving MCMI ( $n = 17$ ) compared to the APM group ( $n = 16$ ) had similar pain (VAS, 1.2 versus 1.8), higher physical activity levels (Tegner activity scale, 7.5 versus 5.0), and less joint space narrowing (radiographs, 0.48 mm versus 2.13 mm).

**II** Kijowski et al<sup>81</sup> evaluated whether preoperative MRI features were associated with clinical outcomes 1 year later. In 100 patients undergoing APM, clinical outcomes were assessed using the IKDC 2000 and structural integrity was assessed using the Boston Leads Osteoarthritis Knee scoring system. Poorer clinical outcome after surgery was associated with greater severity of cartilage loss and bone edema, specific to the compartment of the meniscal tear. Meniscal root tears were associated with an increased risk for limited improvement in middle-aged and older patients following APM.

**II** Thorlund et al<sup>132</sup> assessed knee muscle strength, including maximal isometric knee extension and flexion, 1-leg hop for distance, and maximum number of 1-leg hops in 30 seconds, and found no difference in change in knee muscle strength from 2 years post APM to 4 years post APM in patients who had undergone APM compared to healthy controls. The KOOS quality of life subscale was lower in patients 4 years after APM (mean  $\pm$  SD,  $78.7 \pm 3.6$ ) compared to healthy controls ( $90.0 \pm 2.7$ ; Cohen  $d = 3.6$ ), with no differences in the other 4 KOOS subscale scores between patients and controls.

## II

A series of publications from a 2-year longitudinal cohort study assessed 82 patients 3 months post APM of the medial meniscus (baseline), with 66 (80%) who returned 2 years later for reassessment (follow-up).<sup>62-64,133</sup> Thirty-eight healthy controls were assessed at baseline and 23 (61%) returned for reassessment 2 years later. At baseline, the operated leg had a lower maximum loading rate during early stance phase of walking compared to healthy controls. The peak vertical force during stance increased (relative to baseline) in the operated leg compared to healthy controls over time.<sup>63</sup> Knee muscle weakness in the operated leg reported at 3 months following surgery compared to controls had recovered 2 years later, such that no differences were observed at follow-up between groups.<sup>64</sup> Higher peak knee adduction moment and knee adduction moment impulse (indicators of knee joint loading) during walking were found in patients 3 months following surgery compared to healthy controls. Knee muscle weakness 3 months following APM was not associated with change in the knee adduction moment over the subsequent 2 years.<sup>62</sup> At baseline, in a subgroup of these patients ( $n = 66$ ), greater varus, valgus, and total knee joint angular laxity were found compared to healthy controls. No differences were observed in change in stiffness over the 2-year period between the operated legs and controls.<sup>133</sup>

## III

Stein et al<sup>126</sup> investigated clinical and radiographic outcomes in patients with an isolated traumatic medial meniscal tear who had undergone a meniscal repair ( $n = 42$ ) or partial meniscectomy ( $n = 39$ ). At long-term follow-up (5-8 years after surgery), 56% of the cohort (meniscal repair, 62%; partial meniscectomy, 51%) returned for follow-up, and osteoarthritis progression was greater in the meniscectomy group (40%) compared to the meniscal repair group (20%). There was no difference between groups in knee function using the Lysholm score (meniscal repair, 91.5; partial meniscectomy, 88.4). Following rehabilitation, 95% of the repair group returned to preinjury activity levels based upon Tegner activity scale measures, compared to 50% in the meniscectomy group.

## III

Scanzello et al<sup>122</sup> investigated whether synovitis in patients undergoing APM ( $n = 33$ ) predicted postoperative symptoms. Synovitis and hyperplasia were assessed via surgical biopsies. In patients with inflammation, Lysholm scores and the physical component summary of the Medical Outcomes Study 12-Item Short-Form Health Survey were worse preoperatively. However, there was no association between synovial inflammation and self-reported symptoms at 16 weeks, 1 year, and 2 years postoperatively.

## III

Kim et al<sup>82</sup> evaluated return to sport after surgery in 56 athletes undergoing APM. Athletes younger than 30 years returned to sport on average 54 days

following surgery, while those older than 30 years returned to sports later, on average 89 days following surgery. Patients with medial meniscus tears had a longer return-to-sport time (79 days) than those with lateral meniscus tears (61 days). Elite and competitive athletes had shorter return-to-sport time (53-54 days) than recreational athletes (88 days). Therefore, age, level of physical activity, and which meniscus is torn may influence time to return to sport.

## Articular Cartilage

## I

Goyal et al<sup>58</sup> performed a systematic review of level I and II studies on microfracture surgery, reporting on 6 studies with long-term follow-up and 9 with short-term follow-up. Patients with small articular cartilage lesions (less than 5 cm<sup>2</sup>) treated with microfracture surgery who returned to low-load activities postoperatively had good short-term outcomes. Patients with small lesions who returned to higher-demand activities had an increased progressive failure rate. For large lesions (greater than 4 cm<sup>2</sup>), self-reported outcomes improved up to 5 years after microfracture surgery. The authors of the review reported that younger patients, regardless of lesion size, had better outcomes than older patients.

## I

Goyal et al<sup>57</sup> performed a systematic review of level I and II studies on osteochondral transfer (OCT) procedures, compared to other articular cartilage repair procedures. They reported that high-demand athletes with OCT had superior clinical and self-reported outcome measures compared to athletes with microfracture surgery. Additionally, 93% of athletes with OCT returned to sports, compared to 52% after microfracture. At 10-year follow-up, 75% of athletes with OCT maintained their same level of sports, compared to 37% after microfracture.

## II

In a systematic review, Campbell et al<sup>27</sup> reported 20 studies involving 970 individuals on return to preinjury sport level, with 78% among athletic populations returning after articular cartilage surgeries. In patients after specific articular cartilage repair procedures, 75% returned after microfracture surgery, 84% to 86% after ACI surgeries, and 88% to 89% after OCT surgeries. The average time to return to sports was 11.2 months after articular cartilage surgical procedures. The average time to return to sports after microfracture was 8.6 months, after ACI was 16.0 months, and after OCT surgeries was 7.1 to 9.6 months. The majority of total patients (72%) returned to sports at their preinjury level, with 69% returning after microfracture, 71% to 76% after ACI, and 70% to 79% after OCT surgeries.

## II

In a systematic review, Filardo et al<sup>50</sup> reported on failure rates after ACI surgeries (5-12 years post surgery) in 193 patients. They reported that failure

rates varied based on the definition criteria: (1) surgical: the percentage of patients needing revision surgery (10.4% failure rate), (2) clinical improvement based on minimally clinically important difference (MCID) on the IKDC 2000 (21.2% failure rate), (3) absolute IKDC 2000 scores less than 60 (24.4% failure rate), or (4) IKDC clinical knee scores that were “severely abnormal” (3.6% failure rate). When all criteria were combined, the failure rate was 33.7% at a mean follow-up of 8.5 years.

**II** Harris et al<sup>65</sup> performed a systematic review of failures and reoperation rates after ACI procedures, reporting on 82 studies involving 5276 patients. They reported that the overall failure rate was 5.8%; with first-generation ACI, the failure rate was 1.5% to 7.7%, and with second-generation ACI, the failure rate was 0.83% to 3.3%. Thirty-three percent (33.3%) required a reoperation after primary ACI surgery, with a mean time to reoperation of 21.6 months.

**II** Chalmers et al<sup>30</sup> performed a systematic review of patient-reported outcomes after microfracture, osteochondral autograft, and ACI procedures from preoperation to 2 years after surgery. They reported that patients with ACI had better 1-year Tegner (4.6 versus 3.0) and 2-year IKDC 2000 (82.6 versus 72.6) scores compared to those with microfracture, whereas those with microfracture had better 1-year Lysholm (82.5 versus 73.7) scores compared to those with ACI. They reported that patients with osteochondral autograft had better 1-year Tegner (5.0 versus 3.0) scores, 2-year Marx activity rating scale (7.3 versus 3.7) scores, and 2-year SF-36 (53.5 versus 47.3) scores compared to those with microfracture, whereas those with microfracture had better 1-year Lysholm (82.5 versus 68.3) scores compared to those with osteochondral autograft.

**II** Howard et al<sup>70</sup> evaluated patient-reported outcomes in 48 (60% men) patients prior to and 3, 6, and 12 months after ACI surgery. When comparing scores prior to surgery to 6 and 12 months after surgery, mean  $\pm$  SD IKDC 2000 scores improved from  $38.4 \pm 12.50$  to  $51.1 \pm 18.3$  and  $56.2 \pm 20.6$ , respectively; Lysholm scores improved from  $47 \pm 18$  to  $61 \pm 23$  and  $65 \pm 24$ , respectively; and mean WOMAC scores improved from  $33 \pm 17$  to  $22 \pm 19$  and  $20 \pm 19$ , respectively.

**II** Mithoefer et al,<sup>99</sup> in a systematic review, reported on 20 studies involving 1363 patients after articular cartilage repair, with a mean  $\pm$  SD of  $73\% \pm 5\%$  of patients returning to sports. In patients after specific articular cartilage repair procedures,  $66\% \pm 6\%$  returned after microfracture surgery,  $67\% \pm 17\%$  after ACI surgeries, and

$91\% \pm 2\%$  after OAT surgeries. The time to return to sports varied from 7 to 18 months, depending on the surgical procedure. Time to return to sports after microfracture was  $8 \pm 1$  months, after ACI was  $18 \pm 4$  months, and after OAT was  $7 \pm 2$  months. The majority of patients ( $68\% \pm 4\%$ ) returned to sports at their preinjury level, with  $68\% \pm 5\%$  returning after microfracture,  $71\% \pm 12\%$  after ACI, and  $70\% \pm 3\%$  after OAT.

## 2018 Summary

The clinical course for most patients after meniscus injury managed with or without surgery is satisfactory, though these patients will report lower knee function compared to the general population. Patients who have nonoperative management for meniscus tear have similar to better outcomes in terms of strength and perceived knee function in the short term and intermediate term compared to those who had APM.

Impairments in proprioception and muscle strength and poor patient-reported outcomes are present early after meniscal injury and in the short-term time period (less than 6 months) after APM. Most of these impairments and limitations in patient-reported outcomes may resolve within 2 years after APM. However, perceived knee function and quality of life are lower than for healthy controls as much as 4 years after APM. Demographics, meniscus tear location, physical impairments, and functional levels as determined by performance-based tests and patient-reported outcomes can influence return-to-sport rates after APM.

Young patients who have meniscus repair have similar to better perceived knee function, less activity loss, and higher rates of return to activity compared to those who have APM. Elite and competitive athletes or athletes younger than 30 years are likely to return to sport less than 2 months after APM, and athletes older than 30 years are likely to return by 3 months after APM.

Athletes with OAT procedures have a higher rate of self-reported knee function, return to sports, and maintenance of level of activity compared to athletes with ACI or microfracture.

Return to activity after ACI procedures is high, but patients are delayed in their return to sport. Failure rates and reoperation for complications after ACI procedures are high.

Microfracture procedures are most appropriate with good outcomes for small articular cartilage lesions and those returning to low-demand sports. Those with small lesions returning to high-demand sports have a progressively higher failure rate.

**RISK FACTORS****2010 Recommendation**

**C** Clinicians should consider age and greater time from injury as predisposing factors for having a meniscal injury. Patients who participated in high-level sports or had increased knee laxity after an ACL injury are more likely to have late meniscal surgery.

Clinicians should consider the patients' age and presence of a meniscal tear for the odds of having a chondral lesion subsequent to having an ACL injury. The greater a patient's age and longer time from initial ACL injury are predictive factors of the severity of chondral lesions, and time from initial ACL injury is significantly associated with the number of chondral lesions.

**Evidence Update****Meniscus**

**II** A systematic review of 11 studies of risk factors for meniscus tears found strong evidence that older age (greater than 60 years) (odds ratio [OR] = 2.32), male sex (OR = 2.98), work-related kneeling and squatting (OR = 2.69), and climbing more than 30 flights of stairs per day (OR = 2.28) were associated with the occurrence of degenerative meniscus tears.<sup>124</sup> Playing soccer (OR = 3.58) and rugby (OR = 2.84) were strong risk factors for acute meniscus tears. Additionally, delayed ACL reconstruction (OR = 3.50) was a strong risk factor for future medial meniscus tears.

**II** Papalia et al<sup>110</sup> performed a systematic review of 32 studies to identify risk factors of knee osteoarthritis after meniscectomy. The overall mean prevalence of knee osteoarthritis was 53.5% (range, 16%-92.9%). They found strong evidence that medial and lateral meniscectomy and duration of preoperative symptoms were associated with knee osteoarthritis. Consistent evidence was found that the extent of meniscectomy was associated with knee osteoarthritis. Incidence of knee osteoarthritis was reported higher after meniscectomy in those with degenerative meniscus tears compared to those with traumatic tears. Age at surgery, sex, duration of follow-up, cartilage status, body mass index, functional results, and impairments were inconsistent in their association with knee osteoarthritis.

**II** A systematic review of 5 studies with a minimum of 8-year follow-up on factors associated with knee osteoarthritis after partial meniscectomy found normal or nearly normal clinical results based on clinician grading scores, such as IKDC grading or Fairbanks grading, in 80% to 100% of patients.<sup>113</sup> Radiographic evidence of joint degeneration after partial meniscectomy was present in up to 60% of patients.

**II** Rosenberger et al<sup>118</sup> found that women had poorer knee function on the Lysholm scale than men until 48 weeks post APM. Among women, previous knee injury or impairment and lower preoperative fitness level were risk factors for slower postoperative recovery following partial meniscectomy for patients with meniscus tear.

**II** In a study of all meniscal repairs and any concomitant procedures from a New York statewide database, risk factors for meniscectomy after meniscal repairs were identified.<sup>94</sup> Older age (older than 40 years of age) (hazard ratio = 0.53), lateral meniscus injury (hazard ratio = 0.71), and surgeon characteristics (high annual volume of meniscus repairs) (hazard ratio = 0.37) were associated with lower likelihood of subsequent meniscectomy after an initial isolated meniscus repair.

**III** Brambilla et al<sup>19</sup> retrospectively examined the prevalence of associated meniscus and cartilage lesions in ACL reconstruction. They reported an increase of an average of 0.6% of associated lesion for each month of delay of ACL reconstruction. A delay of 12 months for ACL reconstruction increased the odds of developing a medial meniscus tear (OR = 1.81; 95% CI: 1.32, 2.48), and developing a cartilage lesion on the medial femoral condyle (OR = 2.35; 95% CI: 1.50, 3.68) and on the medial tibial plateau (OR = 5.57; 95% CI: 1.91, 16.26). Male sex increased the odds for developing lateral meniscal tears (OR = 2.29; 95% CI: 1.60, 3.28) and medial meniscal tears (OR = 1.75; 95% CI: 1.28, 2.40).

**III** In a retrospective analysis, Hwang et al<sup>71</sup> investigated the risk factors associated with medial meniscus posterior root tears. Patients with medial meniscus posterior root tears were older, more likely to be female, and had a higher body mass index (greater than 30 kg/m<sup>2</sup>), greater varus mechanical axis angle, lower sports activity level, and higher Kellgren-Lawrence grade than patients with other types of meniscus tears.

**III** In a case-control study, Englund et al<sup>47</sup> reported that any history of meniscus tear (either traumatic or degenerative), independent of meniscectomy and adjusted for patient demographics, physical activity, and mechanical alignment, as compared to no meniscus tear, is highly predictive (OR = 5.7) of the development of radiographic tibiofemoral osteoarthritis.

**III** In a retrospective analysis of 1252 patients in the Kaiser Permanente Anterior Cruciate Ligament Reconstruction Registry, time from injury to ACL reconstruction of greater than 12 months increased the risk of medial meniscus injury at the time of ACL reconstruction. At

the time of ACL reconstruction, women had a lower risk of lateral meniscus injury as compared to men.<sup>31</sup> Increasing age and greater delay in time to ACL reconstruction increased the risk for cartilage injury at the time of ACL reconstruction. A decrease in the rate of medial meniscus repairs relative to medial meniscus injury was associated with delayed time to ACL reconstruction and increasing age.

**III** In a cross-sectional analysis of 2131 knees from the Multicenter Osteoarthritis Study,<sup>35</sup> the risk of meniscus extrusion (meniscal margin extending beyond the tibial margin) from meniscus tears in the medial compartment had an OR of 6.3 and tears in the lateral compartment had an OR of 10.3. Varus and valgus malalignment, and cartilage damage in the medial and lateral compartments, respectively, were also associated with meniscus extrusion.

**IV** In a retrospective analysis of 210 patients with horizontal or radial meniscus tears by Wu et al,<sup>143</sup> the prevalence of radial tears in the posterior horn of the medial meniscus was 25.3% and of horizontal tears in the posterior horn was 26.3%. Higher static varus angle of the knee (OR = 12.58; 95% CI: 2.83, 55.90), older age (OR = 0.88; 95% CI: 0.78, 0.94), and higher Outerbridge grade were risk factors for radial tears in the posterior horn of the medial meniscus.

**IV** In a retrospective analysis of 129 patients with ACL reconstruction, delay in ACL reconstruction of greater than 24 weeks was identified as a risk factor of medial, lateral, or both meniscus tears at time of surgery.<sup>72</sup>

### Articular Cartilage

**I** Pestka et al<sup>112</sup> evaluated clinical outcomes after MACI using the IKDC 2000 questionnaire. They reported that patients with IKDC 2000 scores greater than 80 at 6 (100% probability), 12 (91% probability), and 24 months (89% probability) after surgery were more likely to have IKDC 2000 scores greater than 80 at 36 months, whereas patients with IKDC 2000 scores less than 65 at 12 (61% probability) and 24 months (81% probability) after surgery were more likely to show no improvement (IKDC 2000 score greater than 65) by 36 months.

**I** In a retrospective analysis of 454 patients, Salzmann et al<sup>121</sup> found that absence of previous knee trauma, longer symptom duration, female sex, and previous surgery to the index knee predicted lower IKDC 2000 scores in all patients undergoing microfracture surgery. In patients who failed microfracture surgery, absence of previous knee trauma, longer symptom duration, lower preop-

erative pain and function, smoking, and follow-up time were predictive of lower IKDC 2000 scores. Lower preoperative pain and function, smoking, and patellofemoral lesions were related to higher probability of reoperation.

**I** Jungmann et al,<sup>77</sup> in a study of 88 patients, reported that women (OR = 1.7) and having previous multiple knee surgeries (OR = 4.0), previous bone marrow stimulation procedures (OR = 1.9), and periosteum patch-covered ACI (OR = 2.0-2.4) were associated with significantly higher risk of surgical revision of the index knee.

**II** Ebert et al<sup>42</sup> performed a retrospective analysis of 104 patients (62 men; mean  $\pm$  SD age, 37.9  $\pm$  11.6 years). They reported that higher preoperative SF-36 mental and physical component summary scores, and shorter duration of symptoms, were associated with more favorable KOOS sports/recreation scores 5 years after MACI. Younger age, higher SF-36 mental component scores, shorter duration of symptoms, fewer previous knee procedures, and smaller graft size predicted better 5-year MRI scores. Earlier return to full weight bearing was associated with higher 5-year patient satisfaction scores.

**III** In a case-control study of 122 patients, people with a higher body mass index prior to ACI procedure were more likely to have poorer knee function as reported by the modified Cincinnati scores 24 months after surgery, independent of other demographic and lesion characteristics.<sup>73</sup>

### Meniscus and Articular Cartilage

**I** In a prospective, longitudinal observational study of 152 women older than 40 years of age, Crema et al<sup>34</sup> reported that cartilage loss in the medial tibia (total medial tibia and external medial tibia regions) was positively associated with complex medial meniscus tears or medial meniscus maceration. However, cartilage loss in the medial femoral condyle was not associated with single medial meniscus tears.

**III** Kluczynski et al,<sup>84</sup> in a prospective case-control study of 541 patients, reported that male sex was positively associated with overall lateral meniscus tears in patients undergoing ACL reconstruction, while male sex and delayed surgery up to 6 weeks were associated with lateral meniscus tear surgical management. Male sex, obesity, sports injuries, and a greater number of instability episodes were identified as risk factors for medial meniscus tears in patients undergoing ACL reconstruction and medial meniscus tear surgical management. Older age, obesity, and delayed surgery up to 12 weeks were associated with chondral lesions in patients undergoing ACL reconstruction.

## IV

Among 103 patients (range, 14–85 years of age) prospectively followed, individuals with isolated root and radial/flap meniscus tears had greater articular cartilage degeneration on the medial femoral condyle.<sup>68</sup> Those with isolated root and complex meniscus tears had more articular cartilage degeneration on the medial tibial plateau, whereas those with isolated radial/flap meniscus tears had more articular cartilage degeneration on the lateral tibial plateau. An increase in age and body mass index decreased the Noyes lateral compartment score for a bucket handle/vertical meniscus tear, and an increase in age decreased the Noyes medial compartment score for a bucket handle/vertical meniscus tear.

## IV

In a case series of 97 patients, symptoms lasting more than 6 months after initial injury (OR = 4.98) and a wedge-shaped (asymmetrical) discoid lateral meniscus (OR = 5.36) were associated with the number of articular cartilage lesions as observed on arthroscopy.<sup>40</sup>

## 2018 Summary

Cutting and pivoting sports are risk factors for acute meniscus tears. Increased age and delayed ACL reconstruction are risk factors for future medial and lateral meniscus tears. Female sex, older age, higher body mass index, lower physical activity, and delayed ACL reconstruction are risk factors for medial meniscus tears. Female sex, older age, higher body mass index, longer symptom duration, previous procedures and surgeries, and lower self-reported knee function are associated with higher failures with articular cartilage repair surgical procedures.

## DIAGNOSIS/CLASSIFICATION

### 2010 Summary

The ICD diagnosis of a meniscal tear and the associated ICF diagnosis of joint pain and mobility impairments are made with a fair level of certainty when the patient presents with the following clinical findings<sup>9,14,21,67,93,98,119</sup>:

- Twisting injury
- Tearing sensation at time of injury
- Delayed effusion (6–24 hours post injury)
- History of “catching” or “locking”
- Pain with forced hyperextension
- Pain with maximum passive knee flexion
- Pain or audible click with McMurray’s maneuver
  - Sensitivity, 55% (95% CI: 50%, 60%)
    - Medial meniscus, 50% (95% CI: 38%, 62%)
    - Lateral meniscus, 21% (95% CI: 9%, 43%)
  - Specificity, 77% (95% CI: 62%, 87%)
    - Medial meniscus, 77% (95% CI: 57%, 90%)
    - Lateral meniscus, 94% (95% CI: 85%, 98%)
- Joint-line tenderness

- Sensitivity, 76% (95% CI: 73%, 80%)
  - Medial meniscus, 83% (95% CI: 71%, 90%)
  - Lateral meniscus, 68% (95% CI: 46%, 85%)
- Specificity, 77% (95% CI: 64%, 87%)
  - Medial meniscus, 76% (95% CI: 55%, 89%)
  - Lateral meniscus, 97% (95% CI: 89%, 99%)
- Discomfort or a sense of locking or catching in the knee over either the medial or lateral joint line during the Thessaly test when performed at 20° of knee flexion
  - Sensitivity
    - Medial meniscus, 59% to 89%
    - Lateral meniscus, 67% to 92%
  - Specificity
    - Medial meniscus, 83% to 97%
    - Lateral meniscus, 95% to 96%
- Meniscal Pathology Composite Score: the combination of history of “catching” or “locking,” pain with forced hyperextension, pain with maximum passive knee flexion, joint-line tenderness, and pain or audible click with McMurray’s maneuver
  - Greater than 5 positive findings
    - Sensitivity, 11.2%
    - Specificity, 99.0%
  - Greater than 3 positive findings
    - Sensitivity, 30.8%
    - Specificity, 90.2%
  - Greater than 1 positive finding
    - Sensitivity, 76.6%
    - Specificity, 43.1%
  - Zero positive findings
    - Sensitivity, 23.4%
    - Specificity, 56.9%

The ICD diagnosis of an articular cartilage defect and the associated ICF diagnosis of joint pain and mobility impairments are made with a low level of certainty when the patient presents with the following clinical findings<sup>23</sup>:

- Acute trauma with hemarthrosis (0–2 hours) (associated with osteochondral fracture)
- Insidious onset aggravated by repetitive impact
- Intermittent pain and swelling
- History of “catching” or “locking”
- Joint-line tenderness

### Evidence Update

None.

### 2018 Summary for Diagnosing Meniscal Lesions

Clinical findings of knee pain, history of twisting knee mechanism injury, history of “catching” or “locking,” delayed onset of effusion, and a Meniscal Pathology Composite Score greater than 3 positive findings may be used to classify patients with knee pain and mobility disorders into the

ICD category of tear of the meniscus and the associated ICF impairment-based categories of knee pain (**b28016 Pain in joint**) and mobility impairments (**b7100 Mobility of a single joint**).

### 2018 Summary for Diagnosing Articular Cartilage Lesions

The clinical findings of intermittent knee pain, history of acute trauma to the knee, history of “catching” or “locking” effusion, and joint-line tenderness may classify patients with knee pain and mobility disorders into the ICD category of tear of the articular cartilage and the associated ICF impairment-based categories of knee pain (**b28016 Pain in joint**) and mobility impairments (**b7100 Mobility of a single joint**).

### Decision Tree Model

A pathoanatomical/medical diagnosis of meniscus/articular cartilage lesion can provide valuable information in describing tissue pathology and may assist in nonoperative or preoperative planning and predicting prognosis. The proposed model for examination, diagnosis, and treatment planning for patients with knee pain and mobility impairments associated with knee meniscus/articular cartilage lesions uses the following components: (1) medical screening; (2) classify the condition through evaluation of clinical findings suggestive of musculoskeletal impairments of body functioning (ICF) and associated tissue pathology/disease (ICD); (3) determination of irritability stage; (4) determination of evaluative outcome measure instruments; and (5) intervention strategies for patients with meniscus/articular cartilage lesions with respect to postsurgical care. This model is depicted in the **FIGURE**.

#### Component 1

Medical screening incorporates the findings of the history and physical examination to determine whether the patient's symptoms originate from a condition that requires referral to another health care provider. The Ottawa knee rules are one example of tools that may be helpful in this decision-making process. In addition to those conditions that require a provider referral, clinicians should screen for the presence of psychosocial issues that may affect prognosis and rehabilitation treatment decision making. Psychological stress negatively influences recovery. Fear of reinjury is a frequently cited reason that athletes do not return to sport or reduce their level of physical activity.<sup>5,6</sup> Low internal health locus of control (the belief in one's ability to control one's life), lower self-efficacy, and depressive symptoms prior to surgery result in worse outcomes after ACL reconstruction.<sup>53,131</sup> Athletes who did not return to sport after ACL reconstruction had significantly lower preoperative motivation and more negative psychological response than those who did return.<sup>7</sup> Accordingly, identifying cognitive behavioral tendencies during the patient's evaluation can direct

the therapist to employ specific patient education strategies to optimize patient outcomes from physical therapy interventions and potentially provide indications for referring the patient for consultation with another medical or mental health practitioner.<sup>15</sup>

#### Component 2

Differential evaluation of musculoskeletal clinical findings is to determine the most relevant physical impairments associated with the patient's reported activity limitations and medical diagnosis.<sup>79</sup> Clusters of these clinical findings are described as impairment patterns in the physical therapy literature, and are labeled according to the key impairment(s) of body function associated with that cluster. The ICD-10 and primary and secondary ICF codes associated with meniscus/articular cartilage lesions are provided in the 2010 ICF-based meniscus/articular cartilage lesions CPG.<sup>91</sup> These impairment patterns impact the selection of interventions, which focus on normalizing the key impairments of body function, which in turn improves the movement and function of the patient and lessens or alleviates the activity limitations commonly reported by the patients who meet the diagnostic criteria of that specific pattern. The **FIGURE** lists the key clinical findings used to rule in or rule out the common impairment patterns, and their associated medical conditions. Impairment-based classification is critical for matching the intervention strategy that is most likely to provide the optimal outcome for a patient's clinical findings.<sup>79</sup> However, it is important for clinicians to understand that the impairment pattern, the most relevant impairments of body function, and the associated intervention strategies often change during the patient's episode of care. Thus, continual re-evaluation of the patient's response to treatment and the patient's emerging clinical findings are important for providing optimal interventions throughout the patient's episode of care.<sup>17</sup>

#### Component 3

*Irritability* is a term used by rehabilitation practitioners to reflect the tissue's ability to handle physical stress,<sup>101</sup> and is presumably related to physical status and the extent of injury and inflammatory activity that is present. There are cases where the irritability level and the duration of symptoms do not match, requiring clinicians to make judgments when applying time-based research results to individual patients.<sup>17</sup> Diagnosis of tissue irritability is important for guiding the clinical decisions regarding treatment frequency, intensity, duration, and type, with the goal of matching the optimal dosage of treatment to the status of the tissue being treated.<sup>17,79</sup> There are other biopsychosocial elements that may relate to staging of the condition, including, but not limited to, the level of disability reported by the patient and activity avoidance.<sup>32</sup>

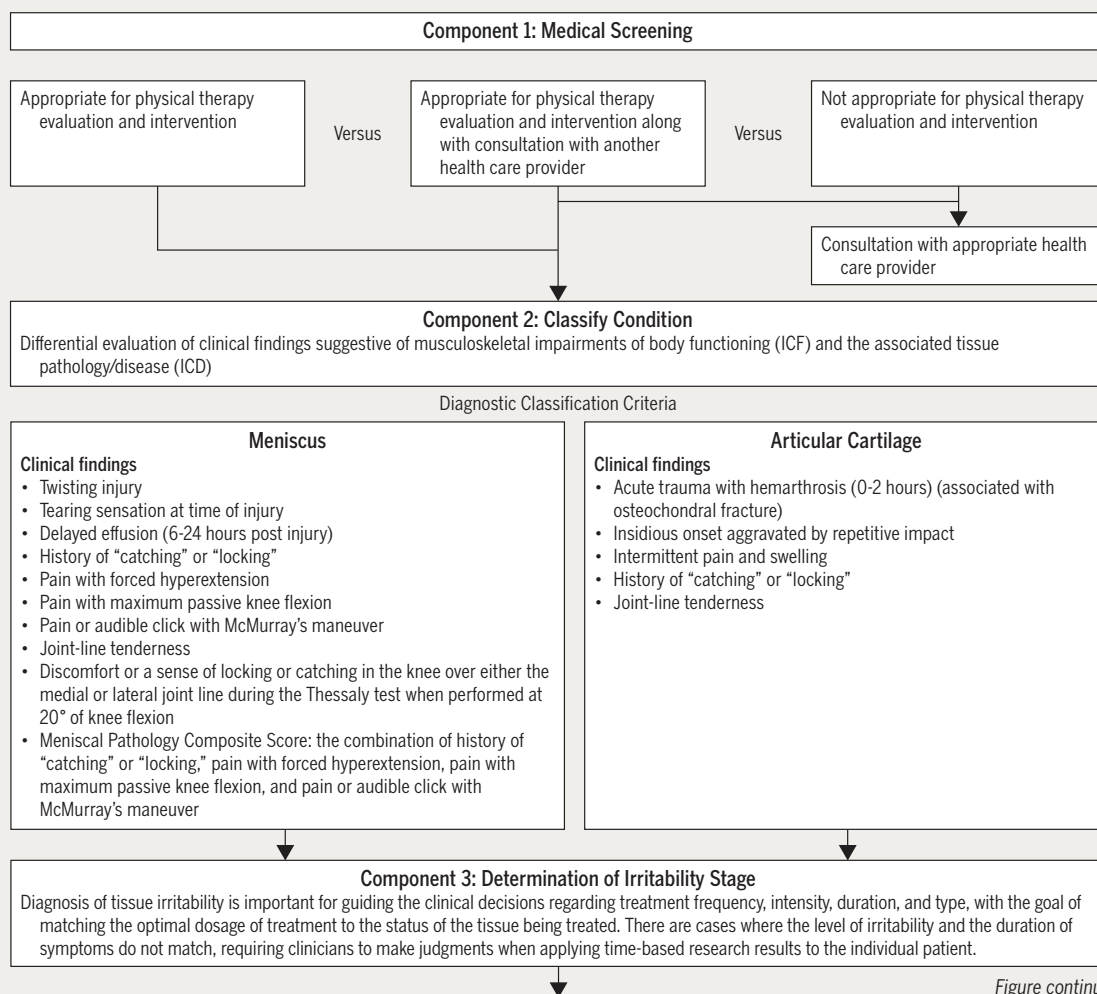


Figure continues on page A18.

**FIGURE.** Model of diagnosis, examination, and treatment of knee pain and mobility impairments. A, guidelines based on strong evidence; B, guidelines based on moderate evidence; C, guidelines based on weak evidence; D, conflicting evidence; E, guidelines based on theoretical/foundational evidence; F, guidelines based on expert opinion.

### Component 4

Outcome measures are standardized tools used for measuring a specific domain, whether it is a body structure or function, activity limitation, or participation restriction, or for determining a specific end point. They are important in direct management of individual patient care, and they provide the opportunity to collectively compare care and determine effectiveness through the repeated application of a standardized measurement. Outcomes in clinical practice provide the mechanism by which the health care provider, the patient, the public, and the payer are able to assess the end results of care and its effect upon the health of the patient and society. Outcome measurement can identify baseline pain, function, and disability, assess global knee function, determine readiness to return to activities, and monitor changes in status throughout treatment. Outcome measures can be classified as patient-reported outcome measures, physical performance measures, and physical impairment measures.

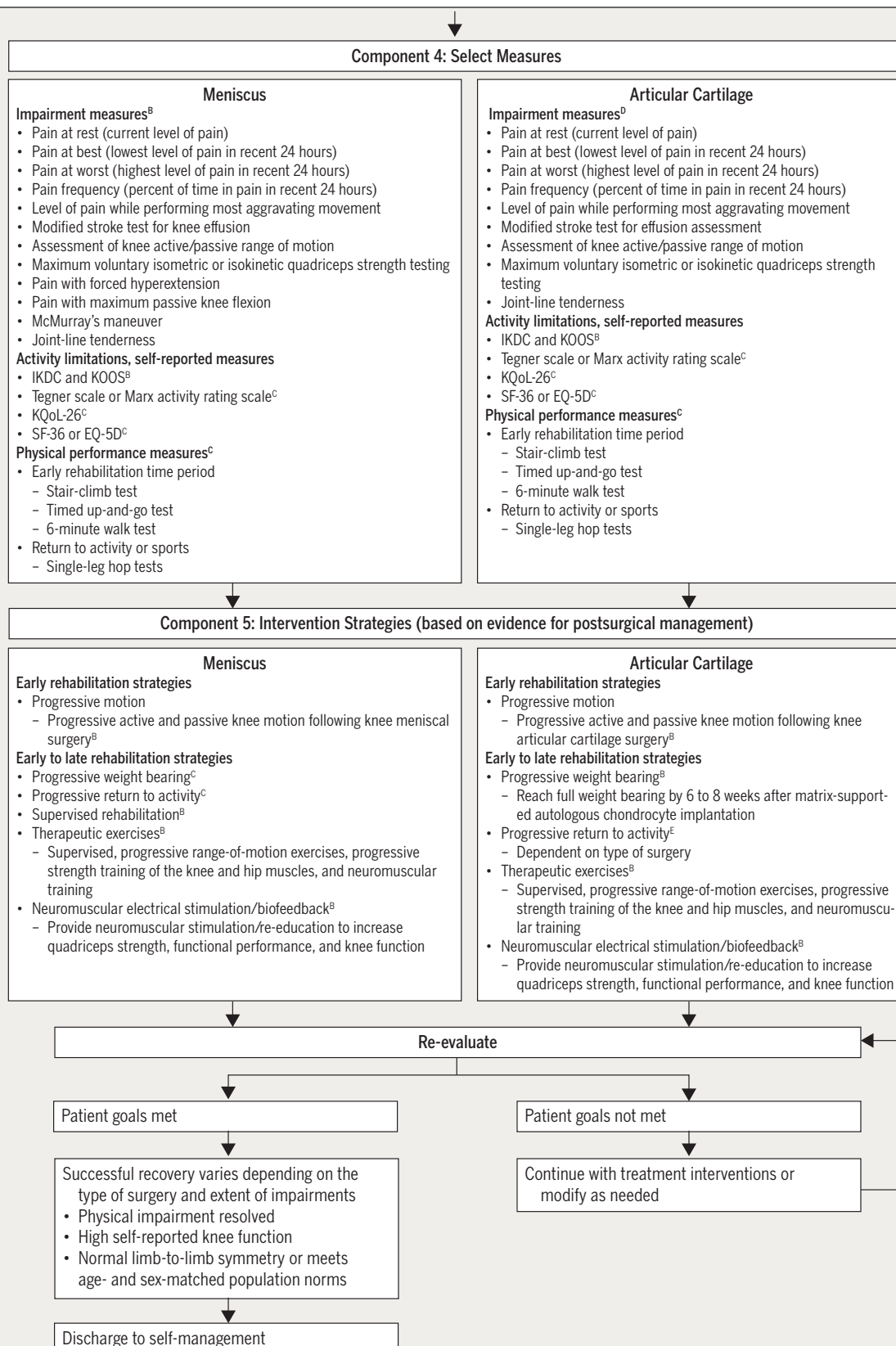
### Component 5

Tear pattern of the meniscus or the size of the articular cartilage lesion and clinical signs and symptoms have typically guided the clinical decision making of treatment interventions primarily for the type of surgical intervention. Interventions are listed by phase of rehabilitation (early, early to late phase). Because irritability level often reflects the tissue's ability to accept physical stress, clinicians should match the most appropriate intervention strategies to the irritability level of the patient's condition.<sup>17,79</sup> Additionally, clinicians should consider influences from psychosocial factors<sup>5-7</sup> in patients with conditions in all stages of recovery.

## DIFFERENTIAL DIAGNOSIS

### 2010 and 2018 Summary

Clinicians should consider diagnostic classifications associated with serious pathological conditions or psychosocial factors when the patient's reported activity limitations or impair-



**FIGURE (CONTINUED).** Model of diagnosis, examination, and treatment of knee pain and mobility impairments. A, guidelines based on strong evidence; B, guidelines based on moderate evidence; C, guidelines based on weak evidence; D, conflicting evidence; E, guidelines based on theoretical/foundational evidence; F, guidelines based on expert opinion.

ments of body function and structure are inconsistent with those presented in the diagnosis/classification section of this guideline, or when the patient's symptoms are not resolving with appropriate interventions.

## IMAGING STUDIES

### 2010 and 2018 Summary (unchanged from 2010)

When a patient reports a history of knee trauma, the therapist needs to be alert for the presence of a fracture in associated lower extremity bones. The Ottawa knee rule has been developed and validated to assist clinicians in determining when to order radiographs in individuals with acute knee injury.<sup>12,127</sup> The Ottawa knee rule has a sensitivity of 0.99 and specificity of 0.49.<sup>12</sup> A knee radiograph series is required in patients with any of the following criteria:

- Aged 55 years or older

- Isolated tenderness of patella (no bone tenderness of knee other than patella)
- Tenderness of head of the fibula
- Inability to flex knee to 90°
- Inability to bear weight both immediately and in the emergency department for 4 steps regardless of limping

Clinical examination by well-trained clinicians appears to be as accurate as MRI in regard to the diagnosis of meniscal lesions.<sup>10,85,95</sup> A lower threshold of suspicion of a meniscal tear is warranted in middle-aged and elderly patients.<sup>59,95</sup> Magnetic resonance imaging may be reserved for more complicated or confusing cases<sup>85</sup> and may assist an orthopaedic surgeon in preoperative planning and prognosis.<sup>85,95</sup> Imaging may be used to monitor the status of meniscus repair or articular cartilage repair or restoration procedures.<sup>25,104</sup>

## CLINICAL GUIDELINES

# Examination

### OUTCOME MEASURES – ACTIVITY LIMITATIONS/ SELF-REPORTED MEASURES

#### 2010 Recommendation

**B** Clinicians should use a validated patient-reported outcome measure, a general health questionnaire, and a validated activity scale for patients with knee pain and mobility impairments. These tools are useful for identifying a patient's baseline status relative to pain, function, and disability and for monitoring changes in the patient's status throughout the course of treatment.

#### Evidence Update

**II** The KOOS has been evaluated for its reliability and validity in people with articular cartilage lesions.<sup>45</sup> Using qualitative methodology, content validity of the KOOS was demonstrated in people who had undergone, or were candidates for, articular cartilage repair. In the quantitative analysis, KOOS subscales showed test-retest reliability (all intraclass correlation coefficients [ICCs] greater than 0.70), and construct validity was demonstrated against the SF-36, although correlation between the KOOS quality of life subscale and SF-36 general health was nonsignificant. The KOOS showed sensitivity to change from baseline to 12 months after baseline, with standardized response means from 0.8 to 1.2 and minimal detectable change estimates ranging between 7.4 and 12.1.

**II** The psychometric properties (internal consistency, convergent validity, sensitivity to change, and floor and ceiling effects) of the generic European Quality of Life-5 Dimensions (EQ-5D) and Medical Outcomes Study Short Form-6 Dimensions (SF-6D) were compared to the knee-specific Hughston Clinic Questionnaire (HCQ) in 84 patients on average 5 days, 6 weeks, and 6 months following APM.<sup>56</sup> The EQ-5D was more consistently responsive to change over time, was better at distinguishing differences between groups, and better reflected the results of the joint-specific HCQ than the SF-6D. Thus, in this patient population, the EQ-5D is preferable to the SF-6D when used alongside a knee-specific instrument such as the HCQ.

**II** The Knee Quality of Life 26-item questionnaire (KQoL-26) for patients with a suspected ligamentous or meniscal injury contains 26 items with 3 subscales of knee-related quality of life: physical functioning, activity limitations, and emotional functioning.<sup>54</sup> The KQoL-26 was found to have evidence for internal reliability (Cron-

bach  $\alpha = .91-.94$ ), test-retest reliability (estimates of 0.80-0.93), construct validity (correlations with other knee scales including Lysholm knee scale:  $r = 0.58-0.76$  with the 3 KQoL-26 subscales; EQ-5D questionnaire:  $r = 0.21-0.54$  with the 3 KQoL-26 subscales; SF-36:  $r = 0.39-0.64$  with the 3 KQoL-26 subscales; and knee symptom questions), responsiveness (effect size: KQoL-26, 0.86-1.13; EQ-5D, 0.46; SF-36, 0.03-0.65 and responsiveness index: KQoL-26, 1.50-2.13; EQ-5D, 0.51; SF-36, 0.03-1.12).

**III** The KOOS has been cross-culturally adapted for use in both the Persian and Arabic languages. In patients from Iran with ACL, meniscus, and combined meniscus and ACL injuries, the Persian version had test-retest reliability (ICCs) on all subscales greater than 0.70, except the KOOS sports/recreation subscale (ICC = 0.61), and the Persian KOOS had good construct validity against the SF-36.<sup>120</sup> The Arabic version showed test-retest reliability (ICCs) for all subscales above 0.70, as well as construct validity against subscales of the RAND-36 (Arabic version of SF-36) ( $r = 0.61-0.78$ ) scores of pain in people from Egypt with ACL, meniscus, and combined knee injuries.<sup>4</sup>

**III** The measurement properties of the Dutch-language versions of the IKDC 2000, KOOS, and WOMAC were compared in patients with meniscal tears.<sup>136</sup> The Cronbach alpha for the IKDC 2000 was .90, for KOOS was .97, for KOOS domains was .72 to .95, for WOMAC was .96, and for WOMAC domains was .84 to .95. Test-retest reliability for the IKDC 2000 was 0.93 (95% CI: 0.89, 0.96), for KOOS was 0.93 (95% CI: 0.89, 0.96), and for WOMAC was 0.89 (95% CI: 0.83, 0.93). The standard error of the measurement for the IKDC 2000 was 5.3, for KOOS was 5.4, and for WOMAC was 7.2. The IKDC 2000, KOOS, and WOMAC demonstrated little to no floor or ceiling effects. The KOOS and WOMAC domains performed suboptimally with respect to internal consistency, measurement error, ability to measure true change, and content validity.

**III** In a study of 53 individuals obtained from a sports injury database and electronic medical records system, Balain et al<sup>13</sup> investigated response shift in 3 self-report measures: Lysholm scale, VAS for worst pain, and the modified IKDC 2000 scale. When patients were asked to retrospectively rate their preoperative knee function 6 months following microfracture, retrospective ratings were lower on all 3 scales than ratings completed preoperatively,

suggesting that preoperative disability may have been greater than patients realized prior to surgery. However, adjusting for this response shift did not affect the clinical interpretation of the modified IKDC 2000 scales or the Lysholm scale.

**III** A Rasch model was used to assess the internal construct validity of the Lysholm knee scale in 157 patients with chondral pathology.<sup>123</sup> Fit to the Rasch model with 7 remaining items was achieved after removal of the swelling item. There was a high degree of agreement between the patient and health professional scoring (ICC = 0.90). By removing the swelling item and using unweighted scores, a modified version of the Lysholm knee scale can be used as an outcome measure for knee chondral damage.

**III** A study translated and culturally adapted the Western Ontario Meniscal Evaluation Tool (WOMET) into Turkish and evaluated the reliability and validity of the translated tool in 96 patients with meniscal pathology.<sup>29</sup> Validity of the tool was compared against the Lysholm knee scale and the SF-36. The WOMET had a Cronbach alpha of .89. Test-retest reliability of the Turkish version of the WOMET was  $r = 0.80$  to  $0.87$ , and had correlations with the Lysholm knee scale ( $r = 0.49$ ) and SF-36 physical component and physical scores ( $r = 0.39$ – $0.63$ ). Lower correlations were observed with several SF-36 domains, predominantly mental component and emotional role scores ( $r = 0.03$ – $0.11$ ).

**III** A cross-cultural adaptation of the KOOS into Spanish was evaluated in 20 patients who underwent arthroscopic surgery for knee cartilage defects with a microfracture technique.<sup>137</sup> Validity was assessed against the SF-36. The Spanish KOOS demonstrated adequate test-retest reliability, with ICCs exceeding 0.8 for all domains. Agreement between the Spanish-version KOOS and the SF-36 domains of physical function ( $r = 0.54$ – $0.81$ ) and pain was observed.

### 2018 Recommendation

**B** For knee-specific outcomes, clinicians should use the IKDC 2000 or KOOS (or a culturally appropriate version for patients whose primary language is not English) and may use the Lysholm scale (with removal of the swelling item, and using unweighted scores).

**C** Clinicians may use the Tegner scale or Marx activity rating scale to assess activity level before and after interventions intended to alleviate the physical impairments, activity limitations, and participation restrictions associated with meniscus or articular cartilage lesions; however, these have less evidence support about measurement properties. The SF-36 or the EQ-5D are appropriate general

health measures in this population. The KQoL-26 may be used to assess knee-related quality of life.

## PHYSICAL PERFORMANCE MEASURES

Refer to the 2010 Knee Pain and Mobility Impairments CPG for a list of activity limitation measures and their measurement properties.<sup>91</sup>

### 2010 Recommendation

**C** Clinicians should utilize easily reproducible physical performance measures, such as single-limb hop tests, 6-minute walk test, or timed up-and-go test, to assess activity limitations and participation restrictions associated with their patient's knee pain or mobility impairment and to assess the changes in the patient's level of function over the episode of care.

### Evidence Update

None.

### 2018 Recommendation

**C** Clinicians may administer appropriate clinical or field tests, such as single-legged hop tests (eg, single hop for distance, crossover hop for distance, triple hop for distance, and 6-m timed hop), that can identify a patient's baseline status relative to pain, function, and disability; detect side-to-side asymmetries; assess global knee function; determine a patient's readiness to return to activities; and monitor changes in the patient's status throughout the course of treatment.

## PHYSICAL IMPAIRMENT MEASURES

Refer to the 2010 Knee Pain and Mobility Impairments CPG for a list of physical impairment measures and their measurement properties.<sup>91</sup>

### Evidence Update

**II** A systematic review of 4 articles examined the validity and reliability of tests to assess meniscus tears.<sup>37</sup> They reported that the Thessaly test had fair reliability ( $\kappa = 0.54$ ) based on 1 study of moderate quality. The McMurray and joint-line-tenderness tests had poor reliability ( $\kappa \leq 0.38$ ) based on 3 studies of low to moderate quality.

**II** In a large diagnostic study of 292 patients with knee pathology and 75 healthy controls, Blyth et al<sup>18</sup> examined the diagnostic accuracy of several meniscal tear clinical tests compared to MRI in primary care clinicians. McMurray's test had poor to fair diagnostic accuracy, with sensitivity of 0.58 (95% CI: 0.49, 0.67), specificity of 0.56 (95% CI: 0.45, 0.66), and OR of 1.79 (95% CI: 1.04,

3.09) compared to MRI. The Thessaly test had sensitivity of 0.66 (95% CI: 0.57, 0.74), specificity of 0.39 (95% CI: 0.29, 0.50), and OR of 1.24 (95% CI: 0.71, 2.18) compared to MRI. Apley's test had sensitivity of 0.53 (95% CI: 0.44, 0.62), specificity of 0.53 (95% CI: 0.42, 0.63), and OR of 1.24 (95% CI: 0.73, 2.12) compared to MRI. The joint-line-tenderness test had sensitivity of 0.77 (95% CI: 0.68, 0.84), specificity of 0.26 (95% CI: 0.18, 0.36), and OR of 1.16 (95% CI: 0.63, 2.13) compared to MRI.

**III** Haviv et al<sup>66</sup> investigated the accuracy of joint-line tenderness of meniscus tears in 134 men and 61 women. Joint-line tenderness for medial and lateral meniscus tears in men had sensitivity of 0.50 to 0.58, specificity of 0.74 to 1.00, and diagnostic accuracy of 0.63 to 0.86. Joint-line tenderness for medial and lateral meniscus tears in women had sensitivity of 0.40 to 0.49, specificity of 0.71 to 0.98, and diagnostic accuracy of 0.57 to 0.93.

**III** Snoeker et al<sup>125</sup> investigated the reliability and diagnostic accuracy of deep squat, Thessaly test, and the joint-line-tenderness test. The Thessaly test had a kappa of 0.54, sensitivity of 0.52 to 0.67, specificity of 0.38 to 0.44, positive likelihood ratio of 0.91 to 1.07, and negative likelihood ratio of 0.88 to 1.12. The deep squat test had a kappa of 0.46, sensitivity of 0.75 to 0.77, specificity of 0.36 to 0.42, positive likelihood ratio of 1.20 to 1.29, and negative likelihood ratio of 0.60 to 0.64. The joint-line-tenderness test had a kappa of 0.17.

**IV** Campbell et al<sup>28</sup> examined the association between patients' pain symptom location and arthroscopy findings in patients with meniscus tear. They reported that pain symptom location was not correlated with the location of the meniscus tear.

## 2018 Recommendation

**B** Clinicians should administer appropriate physical impairment assessments of body structure and function, at least at baseline and at discharge or 1 other follow-up point, for all patients with meniscus tears to support standardization for quality improvement in clinical care and research, including the modified stroke test for effusion assessment, assessment of knee active range of motion, maximum voluntary isometric or isokinetic quadriceps strength testing, forced hyperextension, maximum passive knee flexion, McMurray's maneuver, and joint-line tenderness to palpation.

**D** Clinicians may administer the appropriate physical impairment assessments of body structure and function, at least at baseline and at discharge or 1 other follow-up point, for all patients with articular cartilage lesions

to support standardization for quality improvement in clinical care and research, including the modified stroke test for effusion assessment, assessment of knee active range of motion, maximum voluntary isometric or isokinetic quadriceps strength testing, and joint-line tenderness to palpation.

## BEST-PRACTICE POINT

### Essential Data Elements

Clinicians should document the following measures, at least at baseline and discharge or at 1 other follow-up point, for all patients with meniscus tears to support standardization for quality improvement in clinical care and research:

#### *Activity Limitation – Self-report Measures*

- IKDC 2000 and KOOS

#### *Activity Limitation – Physical Performance Measures*

- Early rehabilitation time period
  - 30-second chair-stand test
  - Stair-climb test
  - Timed up-and-go test
  - 6-minute walk test
- Return to activity or sports
  - Single-leg hop tests

#### *Physical Impairment Measures*

- Modified stroke test for effusion assessment
- Assessment of knee active range of motion
- Maximum voluntary isometric or isokinetic quadriceps strength testing
- Forced hyperextension
- Maximum passive knee flexion
- McMurray's maneuver
- Joint-line tenderness

Clinicians should document the following measures, at least at baseline and discharge or at 1 other follow-up point, for all patients with articular cartilage lesions to support standardization for quality improvement in clinical care and research:

#### *Activity Limitation – Self-report Measures*

- IKDC 2000 and KOOS

#### *Activity Limitation – Physical Performance Measures*

- Early rehabilitation time period
  - 30-second chair-stand test
  - Stair-climb test
  - Timed up-and-go test
  - 6-minute walk test
- Return to activity or sports
  - Single-leg hop tests

#### *Physical Impairment Measures*

- Modified stroke test for effusion assessment
- Assessment of knee active range of motion
- Maximum voluntary isometric or isokinetic quadriceps strength testing
- Joint-line tenderness

## CLINICAL GUIDELINES

# Interventions

### PROGRESSIVE KNEE MOTION

#### 2010 Recommendation

**C** Clinicians may utilize early progressive knee motion following knee meniscal and articular cartilage surgery.

#### Evidence Update

**II** In a randomized controlled trial, patients randomized to the supervised active-range-of-motion group ( $n = 14$ ) using an adjustable pedal arm stationary cycle ergometer had significantly better gait measures (presence or absence of antalgic gait and limp during gait) early after partial meniscectomy compared to the control group ( $n = 14$ ) who did not have supervised therapy.<sup>80</sup> No differences were reported between the groups over time in range of motion, effusion, or IKDC 2000 scores.

**II** A systematic review of 4 level III studies on clinical effectiveness of continuous passive motion after articular lesion surgery did not find improved histological outcomes on second-look arthroscopic biopsies or improved radiographic findings greater than 1 year after surgery.<sup>49</sup> Mixed results in clinical outcomes were reported between the continuous passive motion groups and the active-range-of-motion groups.

#### 2018 Recommendation

**B** Clinicians may use early progressive active and passive knee motion with patients after knee meniscal and articular cartilage surgery.

### PROGRESSIVE WEIGHT BEARING

#### 2010 Recommendation

**D** There are conflicting opinions regarding the best use of progressive weight bearing in patients with meniscal repairs or chondral lesions.

#### Evidence Update

**I** Ebert et al<sup>41</sup> randomized 62 patients after MACI to an accelerated weight-bearing group (stepwise progression in weight bearing, with full weight bearing by 8 weeks) or to a standard of care weight-bearing group (5 weeks of 20% partial weight bearing followed by stepwise progression in weight bearing, with full weight bearing by week 11). Three months after MACI, patients in the accelerated group had better KOOS scores compared to those in the

standard of care group (range for KOOS subscales: 11.84 to 83.32 versus 6.82 to 78.55). Both groups demonstrated progressive graft tissue healing over time, with no difference between groups at any time period (no complete graft de-lamination).

**I** Twenty-eight consecutive patients after MACI were randomized to an accelerated weight-bearing group (stepwise progression in weight bearing, with full weight bearing by 6 weeks) ( $n = 14$ ) or to a standard of care weight-bearing group (stepwise progression in weight bearing, with full weight bearing by 8 weeks) ( $n = 14$ ).<sup>43</sup> Six and 12 months after MACI, patients in the accelerated group had better KOOS quality of life scores compared to those in the standard of care group (6 months, 62 versus 50; 12 months, 77 versus 58). Both groups demonstrated progressive graft tissue healing over time, with no difference between groups at any time period.

**I** Thirty-one patients after ACI were randomized to an accelerated weight-bearing group (stepwise progression in weight bearing, with full weight bearing after 6 weeks) or to a standard of care weight-bearing group (stepwise progression in weight bearing, with full weight bearing after 8 weeks).<sup>141</sup> Both groups showed improvement in clinical scores (IKDC 2000 and Tegner scale) and MRI scores over 2 years, but no significant differences between groups were noted at 1 year and 2 years after ACI.

**II** Lind et al<sup>90</sup> randomized 60 patients after isolated meniscal repair to receive either free rehabilitation (restricted range of motion and toe-touch weight bearing and no brace for 2 weeks with unrestricted activity and free range of motion afterward) or restricted rehabilitation (braced toe-touch weight bearing and progressive restricted range of motion for 6 weeks). Patients were followed at 3 months and 1 and 2 years on KOOS and Tegner measures. Patients who underwent repeat arthroscopy demonstrated little to partial healing in approximately one third of patients in each group ( $n = 19$ ). The KOOS and Tegner scores were similar in both groups at 1 and 2 years.

**IV** A retrospective analysis of 34 patients with degenerative medial meniscus tear and knee osteoarthritis using a foot-worn biomechanical device during activities of daily living was assessed before use and 3 months

and 12 months after wearing the device.<sup>44</sup> Using a gait mat, patients had significant improvement in gait velocity, step length, and single-limb support of the involved knee and improved limb symmetry 3 months after device use. These results were maintained 12 months after device use.

### 2018 Recommendation

**C**

Clinicians may consider early progressive weight bearing in patients with meniscal repairs.

**B**

Clinicians should use a stepwise progression of weight bearing to reach full bearing by 6 to 8 weeks after MACI for articular cartilage lesions.

## PROGRESSIVE RETURN TO ACTIVITY

### 2010 and 2018 Recommendation

**C**

Clinicians may utilize early progressive return to activity following knee meniscal repair surgery.

**E**

Clinicians may need to delay return to activity depending on the type of articular cartilage surgery.

## SUPERVISED REHABILITATION

### 2010 Recommendation

**D**

There are conflicting opinions regarding the best use of clinic-based programs for patients following meniscectomy to increase quadriceps strength and functional performance.

### Evidence Update

**II**

A systematic review of 18 RCTs and meta-analysis of 6 RCTs conducted by Dias et al<sup>39</sup> supports the utilization of outpatient physical therapy with a home exercise program compared to a home exercise program alone to improve knee range of motion and self-reported knee function and reduce knee joint effusion in patients after APM. However, the studies were of moderate to high risk of bias.

**II**

In a systematic review of 12 articles conducted by Reid et al,<sup>116</sup> supervised clinic-based rehabilitation or a well-structured home exercise program demonstrated improvements in knee muscle performance and knee function early after partial meniscectomy. However, the evidence is limited on the use of exercise to prevent the development of osteoarthritis or total knee joint arthroplasty.

**II**

In a systematic review by Coppola and Collins,<sup>33</sup> 5 RCTs were identified comparing outcomes of home-based versus supervised outpatient rehabilitation

after meniscectomy. In early and intermediate follow-ups, there was no difference between groups in patient-reported outcomes at 3 weeks and 1 year after meniscectomy. However, the mean scores for these groups were lower than the population norm, which may suggest that patients in both groups were not fully rehabilitated. Two studies<sup>100,138</sup> reported on higher vertical jump height and single hop distances in the supervised rehabilitation group (vertical jump, 22.5 cm; single hop, 113.8 cm) compared to the home-based group (vertical jump, 20.1 cm; single hop distance, 94.7 cm), though both studies had short follow-ups (less than 4 weeks).

**II**

Papalia et al,<sup>111</sup> in a systematic review, evaluated the same 5 RCTs as Coppola and Collins,<sup>33</sup> comparing outcomes between home-based versus supervised outpatient rehabilitation after meniscectomy. They reached similar conclusions that differences were demonstrated in performance-based outcomes (vertical jump height, single hop distance, and knee extensor strength), but not in patient-reported outcomes (Lysholm scale, Tegner score, Hughston questionnaire).

### 2018 Recommendation

**B**

Clinicians should use exercises as part of the in-clinic supervised rehabilitation program after arthroscopic meniscectomy and should provide and supervise the progression of a home-based exercise program, providing education to ensure independent performance.

## THERAPEUTIC EXERCISES

### 2010 Recommendation

**B**

Clinicians should consider strength training and functional exercise to increase quadriceps and hamstrings strength, quadriceps endurance, and functional performance following meniscectomy.

### Evidence Update

**I**

Østerås<sup>107</sup> randomized 42 participants after degenerative meniscectomy to receive either 12 weeks of specialized exercise therapy (n = 22) or no exercise therapy (n = 20). Four participants (2 in each group) were lost to follow-up. Improvements in pain (VAS, 1.9), muscle strength (quadriceps peak torque, 38.1 Nm), and KOOS scores (18.0 points) were significantly higher in the specialized exercise therapy group compared to the no-exercise-therapy group (VAS, 0.6; quadriceps peak torque, 10.4 Nm; KOOS, 6.5) after the intervention period and 12 months later.

**I**

In a similar study, Østerås et al<sup>108</sup> randomized 75 participants with degenerative meniscus tear to receive either 12 weeks of specialized exercise

therapy ( $n = 38$ ) or no physical therapy ( $n = 37$ ). Eleven participants (5 in the exercise group, 6 in the no-therapy group) were lost to follow-up. Improvements in pain, muscle strength, and patient-reported measures were significantly higher in the exercise therapy group compared to the no-therapy group after the intervention period and 12 months later.

**I** Assche et al<sup>11</sup> implemented the same standardized rehabilitation protocol to patients who were initially randomized into an ACI surgery group ( $n = 57$ ) or a microfracture surgery group ( $n = 61$ ). Both groups received the same rehabilitation program consisting of progressive, stepwise weight bearing, joint mobilization exercises, progressive strength training to the knee muscles, neuromuscular training, and return-to-sports integration. The authors reported no differences in recovery between the 2 groups at 2-year follow-up. When assessing patient recovery, activities that were repetitive movements in low-load conditions (range of motion, non-weight-bearing strengthening exercises, proprioceptive exercises) were considered low-load modalities. Patients who had low levels of activity (less than 12 minutes per day of activity) in these low-load modalities had poorer outcomes in quadriceps strength and single-legged hop performance than patients who had high levels of activity (greater than 12 minutes per day of activity) in low-load modalities.

**I** Hall et al<sup>60</sup> performed an RCT to investigate the effects of a neuromuscular training program on knee kinetics, cartilage quality, and physical function during walking and single-legged sit-to-stand after APM. Groups were randomly assigned to the neuromuscular training group or a control group receiving no interventions. The authors reported no differences in peak knee adduction moment, cartilage quality, and physical function. The neuromuscular group was more likely to demonstrate improvements in physical function and overall improvement compared to the control group.

**I** Kise et al<sup>83</sup> randomized 140 participants into 2 treatment groups: exercise therapy ( $n = 70$ ) or APM. Thirteen (19%) of 70 participants crossed over to the APM group and were analyzed in the “as treated group.” The authors reported no clinically relevant differences in KOOS change scores from baseline to 2-year follow-up between groups (0.9 points; 95% CI: -4.3, 6.1). Both groups demonstrated similar improvements from baseline to 2-year follow-up (exercise group, 25.3 points; 95% CI: 21.6, 29.0 and APM group, 24.4 points; 95% CI: 20.7, 28.0). The exercise group had greater improvement in muscle strength at 3 and 12 months ( $P < .03$ ).

**II** Koutras and colleagues<sup>86</sup> randomized 20 male patients after APM to either receive standard rehabilitation augmented with progressive isokinetic muscle strength training or progressive isotonic muscle strength training. Both groups demonstrated a significant improvement in knee extensor and flexor isokinetic strength and single-legged hop limb-to-limb symmetry (knee extensor at 60°/s, 17% improvement; knee flexor at 60°/s, 12% improvement; single hop: 14% improvement; triple hop: 17% improvement; vertical hop: 18% improvement) and in Lysholm scores (17% improvement) over time, but no significant differences were noted between groups.

**II** Lind et al<sup>90</sup> randomized 60 patients after isolated meniscal repair to receive either free rehabilitation (restricted range of motion and toe-touch weight bearing and no brace for 2 weeks with unrestricted activity and free range of motion afterward) or restricted rehabilitation (braced toe-touch weight bearing and progressive restricted range of motion for 6 weeks). Patients were followed at 3 months and 1 and 2 years on KOOS and Tegner measures. Patients who underwent repeat arthroscopy demonstrated little to partial healing in approximately one third of patients in each group ( $n = 19$ ). The KOOS and Tegner scores were similar in both groups at 1 and 2 years.

**III** Della Villa et al<sup>88</sup> evaluated an intensive rehabilitation program in 31 highly competitive male athletes after an ACI procedure compared to a standard program in 34 nonathletic participants after the same ACI procedure. They reported that at 1 year post surgery, the athletic cohort had higher IKDC 2000 scores than the nonathletic cohort (mean  $\pm$  SD, 84.7  $\pm$  11.7 versus 71.3  $\pm$  16.9), and at 5 years (90.7  $\pm$  11.7 versus 75.7  $\pm$  22.4). Both groups had a decrease in Tegner scores from preinjury to 5 years follow-up (athletic cohort: preinjury, 8.3  $\pm$  1.2; 5 years, 7.3  $\pm$  1.6 and nonathletic cohort: preinjury, 5.9  $\pm$  1.3; 5 years, 4.3  $\pm$  2.1). No severe adverse events were reported in either cohort.

**IV** In a retrospective study, 30 patients with nontraumatic posterior root tear of the medial meniscus had supervised physical therapy, focusing on knee range of motion and knee muscle strength for at least 8 weeks, and were prescribed nonsteroidal anti-inflammatory drugs for 8 to 12 weeks.<sup>89</sup> Patients demonstrated significant and clinically meaningful improvements in pain levels (4-point improvement on VAS) and self-reported knee function (13-point improvement in Lysholm scores).

**IV** Neogi et al<sup>102</sup> reported benefit in symptoms and function with 12-week rehabilitation and analgesics (up to 6 weeks) in 37 patients with degenerative

meniscus. Patients demonstrated improvements in Lysholm scores from pretreatment to final follow-up (56 to 79), Tegner scores (2 to 4), and VAS of pain at rest (2 to 0). Despite the improvement, the number of participants with radiographic osteoarthritis had increased by the final follow-up from 24 knees with Kellgren-Lawrence classifications at grades 0 and 1 and 9 knees at stage 2 or greater at pretreatment to 12 knees with grade 0 and 1 and 21 knees at stage 2 or greater at final follow-up.

**IV** Forty-eight patients with full-thickness articular cartilage lesions with poor knee function participated in a 3-month rehabilitation program consisting of cardiovascular training, progressive strength training of the knee and hip muscles, and neuromuscular training.<sup>140</sup> Primary outcome measures were KOOS and IKDC 2000 scores, and isokinetic muscle strength and hop test scores. The authors reported an 83% adherence rate to the rehabilitation program. They reported clinically significant increases in KOOS sports/recreation and KOOS quality of life subscales. Patients also had large positive effects in standardized response means for muscle strength (0.99 to 1.22) and hop performance (0.53 to 0.75). Four (8.3%) patients showed increases in pain and effusion.

#### 2018 Recommendation

**B** Clinicians should provide supervised, progressive range-of-motion exercises, progressive strength training of the knee and hip muscles, and neuromuscular training to patients with knee meniscus tears and articular cartilage lesions and after meniscus or articular cartilage surgery.

## NEUROMUSCULAR ELECTRICAL STIMULATION/BIOFEEDBACK

### 2010 Recommendation

**B** Neuromuscular electrical stimulation can be used with patients following meniscal or chondral injuries to increase quadriceps muscle strength.

### Evidence Update

**II** Akkaya et al<sup>2</sup> conducted a 3-arm RCT in 45 patients after APM comparing (1) a home exercise program (without any biofeedback or electrical stimulation), (2) electromyographic biofeedback to the quadriceps plus a home exercise program, and (3) electrical stimulation to the quadriceps plus a home exercise program. All 3 groups had similar gait measures and muscle performance values (no statistical differences between groups) 2 and 6 weeks after surgery. All groups had significant improvement in pain during walking and Lysholm scores early after partial meniscectomy.

**II** In an RCT, 64 participants were randomized to receive either electromyographic biofeedback (n = 33) or usual care (n = 31) early after meniscal repair.<sup>106</sup> Electromyographic values and KOOS sport/recreation scores were significantly better in the biofeedback group (electromyographic, 16% to 25% higher; KOOS sport/recreation, 6% higher) compared to the usual care group 8 weeks after meniscal repair. However, these differences may not be clinically meaningful.

### 2018 Recommendation

**B** Clinicians should provide neuromuscular stimulation/re-education to patients following meniscus procedures to increase quadriceps strength, functional performance, and knee function.

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## APPENDIX A

## SEARCH STRATEGIES FOR ALL DATABASES SEARCHED

## MEDLINE

((“Menisci, Tibial” [MH]) OR (knee joint [MH] AND (menisc\* [TW] OR “articular cartilage” [TW] OR chondral [TW]))) AND (classif\* [TW])

((“Menisci, Tibial” [MH]) OR (knee joint [MH] AND (menisc\* [TW] OR “articular cartilage” [TW] OR chondral [TW]))) AND (sensitiv\*[Title/Abstract] OR sensitivity and specificity [MeSH Terms] OR diagnos\*[Title/Abstract] OR diagnosis [MeSH: noexp] OR diagnostic [MeSH: noexp] OR diagnosis, differential [MeSH: noexp] OR diagnosis [Subheading: noexp] OR questionnaires [Mesh] OR “disability evaluation” [mesh: noexp] OR questionnaire [tiab] OR questionnaires [tiab] OR instrument [tiab] OR instruments [tiab] OR scale [tiab] OR scales [tiab] OR measurement [tiab] OR measurements [tiab] OR index [tiab] OR indices [tiab] OR score [tiab] OR scores [tiab])

((“Menisci, Tibial” [MH]) OR (knee joint [MH] AND (menisc\* [TW] OR “articular cartilage” [TW] OR chondral [TW]))) AND (physical therapy modalities [MH] OR recovery of function [MH] OR rehabilitation [MH] OR therapeutics [MH] OR “physical therapy” [TW] OR physiother\* [TW] OR recovery [TW] OR restoration [TW] OR re-education [TW] OR early ambulation [MH] OR strengthening [TW] OR resistance training [MH] OR “resistance methods” [TW] OR exercise therapy [MH] OR biofeedback, psychology [MH] OR “neuromuscular electrical stimulation” [TW] OR pain management [MH] OR pain measurement [MH] OR mobilization\* [TW] OR “continuous passive motion” [TW] OR manipulation, spinal [MH] OR ultrasonography [TW] OR ultrasound [TW] OR acupuncture [TW] OR laser\* [TW] OR patient education as topic [MH] OR electrical stimulation [MH] OR electrical stimulation therapy [MH] OR Transcutaneous electric nerve stimulation [MH] OR taping [TW] OR bracing [TW] OR orthotic\* [TW] OR weight-bearing [MH] OR Range of motion [MH] OR Treatment Outcome [MH] OR Exercise [MH] OR “physical therapy treatments” [TW] OR “training program” [TW])

((“Menisci, Tibial” [MH]) OR (knee joint [MH] AND (menisc\* [TW] OR “articular cartilage” [TW] OR chondral [TW]))) AND (prognos\* [tw] OR return to work [tw] OR return to work [MH] OR return to sport [tw])

((“Menisci, Tibial” [MH]) OR (knee joint [MH] AND (menisc\* [TW] OR “articular cartilage” [TW] OR chondral [TW]))) AND (preval\* [tw] OR incidenc\* [tw] OR epidem\* [tw])

((“Menisci, Tibial” [MH]) OR (knee joint [MH] AND (menisc\* [TW] OR “articular cartilage” [TW] OR chondral [TW]))) AND (associat\* [tw] OR risk\* [tw] OR probabili\* [tw] OR odds\* [tw] OR relat\* [tw] OR prevalen\* [tw] OR predict\* [tw] OR caus\* [tw] OR etiol\* [tw] OR interact\* [tw])

## Scopus

((TITLE-ABS-KEY (“menisc\*”) AND (TITLE-ABS-KEY (tibial) OR TITLE-ABS-KEY (medial) OR TITLE-ABS-KEY (lateral))) OR (TITLE-ABS-KEY (semilunar) AND TITLE-ABS-KEY (cartilage\*)) OR (TITLE-ABS-KEY (“knee joint”) AND (TITLE-ABS-KEY (menisc\*) OR TITLE-ABS-KEY (“articular cartilage”) OR TITLE-ABS-KEY (chondral)))) AND (TITLE-ABS-KEY (classif\*))

((TITLE-ABS-KEY (“menisc\*”) AND (TITLE-ABS-KEY (tibial) OR TITLE-ABS-KEY (medial) OR TITLE-ABS-KEY (lateral))) OR (TITLE-ABS-KEY (semilunar) AND TITLE-ABS-KEY (cartilage\*)) OR (TITLE-ABS-KEY (“knee joint”) AND (TITLE-ABS-KEY (menisc\*) OR TITLE-ABS-KEY (“articular cartilage”) OR TITLE-ABS-KEY (chondral)))) AND (TITLE-ABS-KEY (sensitiv\*) OR TITLE-ABS-KEY (sensitivity and specificity) OR TITLE-ABS-KEY (diagnos\*) OR TITLE-ABS-KEY (questionnaires) OR TITLE-ABS-KEY (“disability evaluation”) OR TITLE-ABS-KEY (questionnaire) OR TITLE-ABS-KEY (questionnaires) OR TITLE-ABS-KEY (instrument) OR TITLE-ABS-KEY (instruments) OR TITLE-ABS-KEY (scale) OR TITLE-ABS-KEY (scales) OR TITLE-ABS-KEY (measurement) OR TITLE-ABS-KEY (measurements) OR TITLE-ABS-KEY (index) OR TITLE-ABS-KEY (indices) OR TITLE-ABS-KEY (score) OR TITLE-ABS-KEY (scores))

((TITLE-ABS-KEY (“menisc\*”) AND (TITLE-ABS-KEY (tibial) OR TITLE-ABS-KEY (medial) OR TITLE-ABS-KEY (lateral))) OR (TITLE-ABS-KEY (semilunar) AND TITLE-ABS-KEY (cartilage\*)) OR (TITLE-ABS-KEY (“knee joint”) AND (TITLE-ABS-KEY (menisc\*) OR TITLE-ABS-KEY (“articular cartilage”) OR TITLE-ABS-KEY (chondral)))) AND (TITLE-ABS-KEY (“physical therapy modalities”) OR TITLE-ABS-KEY (“recovery of function”) OR TITLE-ABS-KEY (rehabilitation) OR TITLE-ABS-KEY (therapeutics) OR TITLE-ABS-KEY (“physical therapy”) OR TITLE-ABS-KEY (physiother\*) OR TITLE-ABS-KEY (recovery) OR TITLE-ABS-KEY (restoration) OR TITLE-ABS-KEY (re-education) OR TITLE-ABS-KEY (“early ambulation”) OR TITLE-ABS-KEY (strengthening) OR TITLE-ABS-KEY (“resistance training”) OR TITLE-ABS-KEY (“resistance methods”) OR TITLE-ABS-KEY (“exercise therapy”) OR TITLE-ABS-KEY (biofeedback) OR TITLE-ABS-KEY (“neuromuscular electrical stimulation”) OR TITLE-ABS-KEY (“pain management”) OR TITLE-ABS-KEY (“pain measurement”) OR TITLE-ABS-KEY (mobilization\*) OR TITLE-ABS-KEY (“continuous passive motion”) OR TITLE-ABS-KEY (“spinal manipulation”) OR TITLE-ABS-KEY (ultrasonography) OR TITLE-ABS-KEY (ultrasound) OR TITLE-ABS-KEY (acupuncture) OR TITLE-ABS-KEY (laser\*) OR TITLE-ABS-KEY (“patient education”) OR TITLE-ABS-KEY (“electrical stimulation”) OR TITLE-ABS-KEY (“electrical stimulation therapy”) OR TITLE-ABS-KEY (“Transcutaneous electric nerve stimulation”) OR TITLE-ABS-KEY (taping) OR TITLE-ABS-KEY (bracing) OR TITLE-ABS-KEY (orthotic\*) OR TITLE-ABS-KEY (weight-bearing) OR TITLE-ABS-KEY (“Range of motion”) OR TITLE-ABS-KEY (“Treatment Outcome”) OR TITLE-ABS-KEY (Exercise) OR TITLE-ABS-KEY (“physical therapy treatments”) OR TITLE-ABS-KEY (“training program”))

((TITLE-ABS-KEY (“menisc\*”) AND (TITLE-ABS-KEY (tibial) OR TITLE-

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ABS-KEY (medial) OR TITLE-ABS-KEY (lateral))) OR (TITLE-ABS-KEY (semilunar) AND TITLE-ABS-KEY (cartilage\*)) OR (TITLE-ABS-KEY ("knee joint") AND (TITLE-ABS-KEY (menisc\*) OR TITLE-ABS-KEY ("articular cartilage") OR TITLE-ABS-KEY (chondral))) AND (TITLE-ABS-KEY (prognos\*) OR TITLE-ABS-KEY (return to work) OR TITLE-ABS-KEY (return to sport))

((TITLE-ABS-KEY ("menisc\*") AND (TITLE-ABS-KEY (tibial) OR TITLE-ABS-KEY (medial) OR TITLE-ABS-KEY (lateral))) OR (TITLE-ABS-KEY (semilunar) AND TITLE-ABS-KEY (cartilage\*)) OR (TITLE-ABS-KEY ("knee joint") AND (TITLE-ABS-KEY (menisc\*) OR TITLE-ABS-KEY ("articular cartilage") OR TITLE-ABS-KEY (chondral)))) AND ((TITLE (prevalence) OR KEY (prevalence)) OR (TITLE (incidence) OR KEY (incidence)) OR (TITLE (epidemiology) OR KEY (epidemiology)))

((TITLE-ABS-KEY ("menisc\*") AND (TITLE-ABS-KEY (tibial) OR TITLE-ABS-KEY (medial) OR TITLE-ABS-KEY (lateral))) OR (TITLE-ABS-KEY (semilunar) AND TITLE-ABS-KEY (cartilage\*)) OR (TITLE-ABS-KEY ("knee joint") AND (TITLE-ABS-KEY (menisc\*) OR TITLE-ABS-KEY ("articular cartilage") OR TITLE-ABS-KEY (chondral)))) AND (TITLE-ABS-KEY (associat\*) OR TITLE-ABS-KEY (risk\*) OR TITLE-ABS-KEY (probabil\*) OR TITLE-ABS-KEY (odds\*) OR TITLE-ABS-KEY (relat\*) OR TITLE-ABS-KEY (prevalen\*) OR TITLE-ABS-KEY (predict\*) OR TITLE-ABS-KEY (caus\*) OR TITLE-ABS-KEY (etiolo\*) OR TITLE-ABS-KEY (interact\*))

## CINAHL

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND (TX (classif\*))

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND (TX (sensitiv\*) OR TX (sensitivity and specificity) OR TX (diagnos\*) OR TX (questionnaires) OR TX ("disability evaluation") OR TX (questionnaire) OR TX (questionnaires) OR TX (instrument) OR TX (instruments) OR TX (scale) OR TX (scales) OR TX (measurement) OR TX (measurements) OR TX (index) OR TX (indices) OR TX (score) OR TX (scores))

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND (TX ("physical therapy modalities") OR TX ("recovery of function") OR TX (rehabilitation) OR TX (therapeutics) OR TX ("physical therapy") OR TX (physiother\*) OR TX (recovery) OR TX (restoration) OR TX (re-education) OR TX ("early ambulation") OR TX (strengthening) OR TX ("resistance training") OR TX ("resistance methods") OR TX ("exercise therapy") OR TX (biofeedback) OR TX ("neuromuscular electrical stimulation") OR TX ("pain management") OR TX ("pain

measurement") OR TX (mobilization\*) OR TX ("continuous passive motion") OR TX ("spinal manipulation") OR TX (ultrasonography) OR TX (ultrasound) OR TX (acupuncture) OR TX (laser\*) OR TX ("patient education") OR TX ("electrical stimulation") OR TX ("electrical stimulation therapy") OR TX ("Transcutaneous electric nerve stimulation") OR TX (taping) OR TX (bracing) OR TX (orthotic\*) OR TX (weight-bearing) OR TX ("Range of motion") OR TX ("Treatment Outcome") OR TX (Exercise) OR TX ("physical therapy treatments") OR TX ("training program"))

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND (TX (prognos\*) OR TX (return to work) OR TX (return to sport))

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND ((TI (prevalence) OR SU (prevalence)) OR (TI (incidence) OR SU (incidence)) OR (TI (epidemiology) OR SU (epidemiology)))

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND (TX (associat\*) OR TX (risk\*) OR TX (probabil\*) OR TX (odds\*) OR TX (relat\*) OR TX (prevalen\*) OR TX (predict\*) OR TX (caus\*) OR TX (etiolo\*) OR TX (interact\*))

## SPORTDiscus

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND (TX (classif\*))

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND (TX (sensitiv\*) OR TX (sensitivity and specificity) OR TX (diagnos\*) OR TX (questionnaires) OR TX ("disability evaluation") OR TX (questionnaire) OR TX (questionnaires) OR TX (instrument) OR TX (instruments) OR TX (scale) OR TX (scales) OR TX (measurement) OR TX (measurements) OR TX (index) OR TX (indices) OR TX (score) OR TX (scores))

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND (TX ("physical therapy modalities") OR TX ("recovery of function") OR TX (rehabilitation) OR TX (therapeutics) OR TX ("physical therapy") OR TX (physiother\*) OR TX (recovery) OR TX (restoration) OR TX (re-education) OR TX ("early ambulation") OR TX (strengthening) OR TX ("resistance training") OR TX ("resistance methods") OR

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TX ("exercise therapy") OR TX (biofeedback) OR TX ("neuromuscular electrical stimulation") OR TX ("pain management") OR TX ("pain measurement") OR TX (mobilization\*) OR TX ("continuous passive motion") OR TX ("spinal manipulation") OR TX (ultrasonography) OR TX (ultrasound) OR TX (acupuncture) OR TX (laser\*) OR TX ("patient education") OR TX ("electrical stimulation") OR TX ("electrical stimulation therapy") OR TX ("Transcutaneous electric nerve stimulation") OR TX (taping) OR TX (bracing) OR TX (orthotic\*) OR TX (weight-bearing) OR TX ("Range of motion") OR TX ("Treatment Outcome") OR TX (Exercise) OR TX ("physical therapy treatments") OR TX ("training program"))

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND (TX (prognos\*) OR TX (return to work) OR TX (return to sport))

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND ((TI (prevalence) OR SU (prevalence)) OR (TI (incidence) OR SU (incidence)) OR (TI (epidemiology) OR SU (epidemiology)))

((TX ("menisc\*") AND (TX (tibial) OR TX (medial) OR TX (lateral))) OR (TX (semilunar) AND TX (cartilage\*)) OR (TX ("knee joint") AND (TX (menisc\*) OR TX ("articular cartilage") OR TX (chondral)))) AND (TX (associat\*) OR TX (risk\*) OR TX (probabil\*) OR TX (odds\*) OR TX (relat\*) OR TX (prevalen\*) OR TX (predict\*) OR TX (caus\*) OR TX (etiol\*) OR TX (interact\*))

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((("menisc\*") AND ((tibial) OR (medial) OR (lateral))) OR ((semilunar) AND (cartilage\*)) OR ((("knee joint") AND ((menisc\*) OR ("articular cartilage") OR (chondral)))) AND (classif\*))

((("menisc\*") AND ((tibial) OR (medial) OR (lateral))) OR ((semilunar) AND (cartilage\*)) OR ((("knee joint") AND ((menisc\*) OR ("ar-

ticular cartilage") OR (chondral)))) AND ((sensitiv\*) OR (sensitivity and specificity) OR (diagnos\*) OR (questionnaires) OR ("disability evaluation") OR (questionnaire) OR (questionnaires) OR (instrument) OR (instruments) OR (scale) OR (scales) OR (measurement) OR (measurements) OR (index) OR (indices) OR (score) OR (scores))

((("menisc\*") AND ((tibial) OR (medial) OR (lateral))) OR ((semilunar) AND (cartilage\*)) OR ((("knee joint") AND ((menisc\*) OR ("articular cartilage") OR (chondral)))) AND ((("physical therapy modalities") OR ("recovery of function") OR (rehabilitation) OR (therapeutics) OR ("physical therapy") OR (physiother\*) OR (recovery) OR (restoration) OR (re-education) OR ("early ambulation") OR (strengthening) OR ("resistance training") OR ("resistance methods") OR ("exercise therapy") OR (biofeedback) OR ("neuromuscular electrical stimulation") OR ("pain management") OR ("pain measurement") OR (mobilization\*) OR ("continuous passive motion") OR ("spinal manipulation") OR (ultrasonography) OR (ultrasound) OR (acupuncture) OR (laser\*) OR ("patient education") OR ("electrical stimulation") OR ("electrical stimulation therapy") OR ("Transcutaneous electric nerve stimulation") OR (taping) OR (bracing) OR (orthotic\*) OR (weight-bearing) OR ("Range of motion") OR ("Treatment Outcome") OR (Exercise) OR ("physical therapy treatments") OR ("training program"))

((("menisc\*") AND ((tibial) OR (medial) OR (lateral))) OR ((semilunar) AND (cartilage\*)) OR ((("knee joint") AND ((menisc\*) OR ("articular cartilage") OR (chondral)))) AAND ((prognos\*) OR (return to work) OR (return to sport))

((("menisc\*") AND ((tibial) OR (medial) OR (lateral))) OR ((semilunar) AND (cartilage\*)) OR ((("knee joint") AND ((menisc\*) OR ("articular cartilage") OR (chondral)))) AND ((prevalence) OR (incidence) OR (epidemiology))

((("menisc\*") AND ((tibial) OR (medial) OR (lateral))) OR ((semilunar) AND (cartilage\*)) OR ((("knee joint") AND ((menisc\*) OR ("articular cartilage") OR (chondral)))) AND ((associat\*) OR (risk\*) OR (probabil\*) OR (odds\*) OR (relat\*) OR (prevalen\*) OR (predict\*) OR (caus\*) OR (etiol\*) OR (interact\*))

## APPENDIX B

## SEARCH RESULTS

| Database/Source               | Date Conducted | Results, n | Date Conducted | Results, n | Total, n |
|-------------------------------|----------------|------------|----------------|------------|----------|
| MEDLINE                       | November 2014  | 3773       | December 2016  | 1900       | 5673     |
| Scopus                        | November 2014  | 6692       | December 2016  | 3879       | 10571    |
| CINAHL                        | November 2014  | 2207       | December 2016  | 672        | 2879     |
| SPORTDiscus                   | November 2014  | 5573       | December 2016  | 3044       | 8617     |
| Cochrane Library              | November 2014  | 244        | December 2016  | 218        | 462      |
| Cochrane reviews              |                | 6          |                | 3          | 9        |
| Other reviews                 |                | 15         |                | 3          | 18       |
| Trials                        |                | 221        |                | 204        | 425      |
| Technology assessments        |                | 1          |                | 7          | 8        |
| Economic evaluations          |                | 1          |                | 1          | 2        |
| Total                         |                | 18489      |                | 9713       | 28202    |
| Total with duplicates removed |                | 4990       |                | 2690       | 7680     |
| Total with hand search        |                |            |                | 12         | 7692     |

## APPENDIX C

**CRITERIA FOR INCLUSION AND EXCLUSION OF STUDIES FOR REVIEW**

Articles published in peer-reviewed journals that include studies of the following types: systematic reviews, meta-analyses, experimental and quasi-experimental, cohort, case series, and cross-sectional studies were included.

Exclusions: meeting abstracts, press releases, theses, nonsystematic review articles, case reports, and articles that cannot be retrieved in English.

**Inclusion Criteria**

Articles reporting on isolated and combined injuries for meniscus and articular cartilage injuries:

- The functional anatomy of the menisci and articular cartilage of the tibiofemoral joint

OR

- Tests and measures for diagnosis and/or differential diagnosis of meniscal and chondral lesions within the scope of physical therapist practice, including but not limited to “specific tests and measures”

OR

- Measurement properties of instruments and tests specific to measuring meniscal and chondral lesion-related outcomes (including but not limited to symptoms, functions, activity, and participation)

OR

- Measurement properties of instruments that are not specific to meniscal and chondral lesions BUT are specific to lower extremity outcomes

OR

- Measurement properties of instruments using data from a sample of patients with meniscal and chondral lesions

OR

- Primarily adolescents and adults (12 years old or older)
  - Studies reporting on persons younger than 12 years old IF the proportion in the sample is small (less than 5%) OR with separate data available for adults

AND

- Meniscal and chondral lesions, including the following topics:
  - Risk of meniscal and chondral lesions
  - Diagnostic characteristics of meniscal and chondral lesions, including but not limited to location, duration, and quality, and related impairments and functional limitations
  - Interventions within the scope of practice of physical therapists for meniscal and chondral lesions

All outcome studies were included.

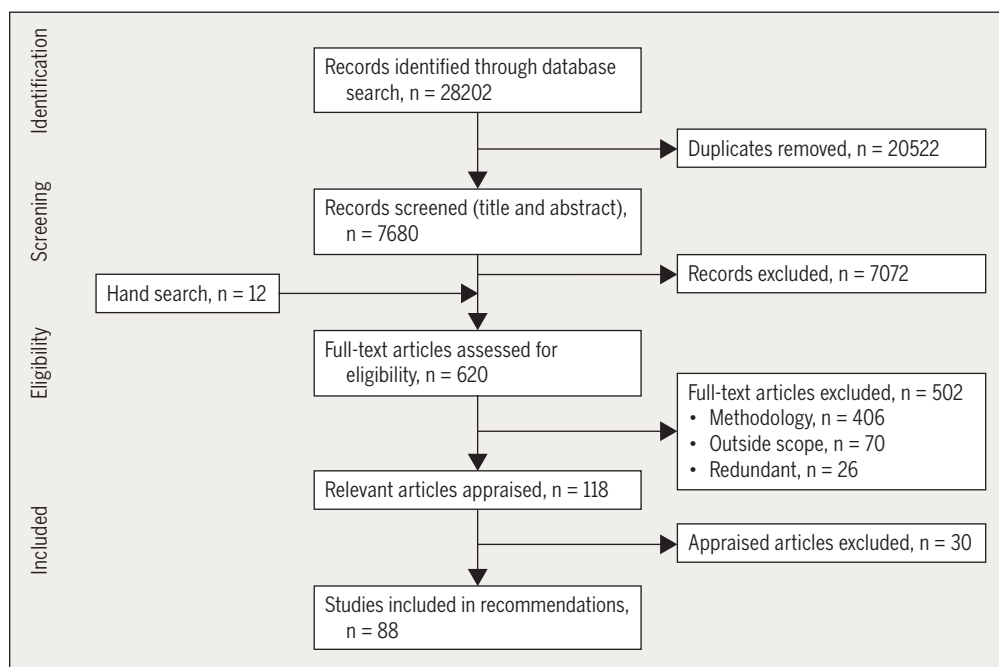
**Exclusion Criteria**

Articles reporting on:

- Osteochondritis dissecans lesions
- Primarily infants and children (younger than 12 years old)
- Ligament-related injuries of the tibiofemoral joint
- Patellofemoral pain, patellar tendinopathy/tendon pain, or iliotibial band
- Nonmusculoskeletal tibiofemoral pain
  - Diabetes
  - Ulcers
  - Primary peripheral nerve entrapment
- Topics outside the scope of physical therapist practice
  - Decisions to order radiologic tests
  - Pharmacological interventions
- Biomechanical studies

## APPENDIX D

## FLOW CHART OF ARTICLES



## APPENDIX E

ARTICLES INCLUDED IN RECOMMENDATIONS  
BY TOPIC

## Impairment/Function-Based Diagnosis

## Incidence

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- Yeh PC, Starkey C, Lombardo S, Vitti G, Kharrazi FD. Epidemiology of isolated meniscal injury and its effect on performance in athletes from the National Basketball Association. *Am J Sports Med.* 2012;40:589-594. <https://doi.org/10.1177/0363546511428601>

## Clinical Course

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## DIAGNOSIS/CLASSIFICATION: DIFFERENTIAL DIAGNOSIS Examination

### Outcome Measures

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## APPENDIX F

## LEVELS OF EVIDENCE TABLE\*

| Level | Intervention/<br>Prevention                                                                                                                                                    | Pathoanatomic/Risk/Clinical<br>Course/Prognosis/Differential<br>Diagnosis                                                                                                                                      | Diagnosis/Diagnostic<br>Accuracy                                                                                                                                                                | Prevalence of<br>Condition/Disorder                                                                                    | Exam/Outcomes                                                                                                            |
|-------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| I     | Systematic review of<br>high-quality RCTs<br>High-quality RCT <sup>†</sup>                                                                                                     | Systematic review of<br>prospective cohort studies<br>High-quality prospective<br>cohort study <sup>‡</sup>                                                                                                    | Systematic review<br>of high-quality<br>diagnostic studies<br>High-quality diagnostic<br>study <sup>§</sup> with validation                                                                     | Systematic review,<br>high-quality cross-<br>sectional studies<br>High-quality cross-<br>sectional study <sup>  </sup> | Systematic review of<br>prospective cohort<br>studies<br>High-quality pro-<br>spective cohort<br>study                   |
| II    | Systematic review of<br>high-quality cohort<br>studies<br>High-quality cohort<br>study <sup>†</sup><br>Outcomes study or<br>ecological study<br>Lower-quality RCT <sup>¶</sup> | Systematic review of retro-<br>spective cohort study<br>Lower-quality prospective<br>cohort study<br>High-quality retrospective<br>cohort study<br>Consecutive cohort<br>Outcomes study or<br>ecological study | Systematic review of<br>exploratory diag-<br>nostic studies or<br>consecutive cohort<br>studies<br>High-quality explor-<br>atory diagnostic<br>studies<br>Consecutive retro-<br>spective cohort | Systematic review of<br>studies that allows<br>relevant estimate<br>Lower-quality cross-<br>sectional study            | Systematic review<br>of lower-quality<br>prospective cohort<br>studies<br>Lower-quality pro-<br>spective cohort<br>study |
| III   | Systematic reviews of<br>case-control studies<br>High-quality case-<br>control study<br>Lower-quality cohort<br>study                                                          | Lower-quality retrospective<br>cohort study<br>High-quality cross-sectional<br>study<br>Case-control study                                                                                                     | Lower-quality explor-<br>atory diagnostic<br>studies<br>Nonconsecutive retro-<br>spective cohort                                                                                                | Local nonrandom<br>study                                                                                               | High-quality cross-<br>sectional study                                                                                   |
| IV    | Case series                                                                                                                                                                    | Case series                                                                                                                                                                                                    | Case-control study                                                                                                                                                                              | ...                                                                                                                    | Lower-quality cross-<br>sectional study                                                                                  |
| V     | Expert opinion                                                                                                                                                                 | Expert opinion                                                                                                                                                                                                 | Expert opinion                                                                                                                                                                                  | Expert opinion                                                                                                         | Expert opinion                                                                                                           |

Abbreviation: RCT, randomized clinical trial.

\*Adapted from Phillips et al<sup>114</sup> (<http://www.cebm.net/index.aspx?o=1025>). See also APPENDIX G.

<sup>†</sup>High quality includes RCTs with greater than 80% follow-up, blinding, and appropriate randomization procedures.

<sup>‡</sup>High-quality cohort study includes greater than 80% follow-up.

<sup>§</sup>High-quality diagnostic study includes consistently applied reference standard and blinding.

<sup>||</sup>High-quality prevalence study is a cross-sectional study that uses a local and current random sample or censuses.

<sup>¶</sup>Weaker diagnostic criteria and reference standards, improper randomization, no blinding, and less than 80% follow-up may add bias and threats to validity.

## APPENDIX G

**PROCEDURES FOR ASSIGNING LEVELS OF EVIDENCE**

- Level of evidence is assigned based on the study design using the Levels of Evidence table (**APPENDIX F**), assuming high quality (eg, for intervention, randomized clinical trial starts at level I)
- Study quality is assessed using the critical appraisal tool, and the study is assigned 1 of 4 overall quality ratings based on the critical appraisal results
- Level of evidence assignment is adjusted based on the overall quality rating:
  - High quality (high confidence in the estimate/results): study remains at assigned level of evidence (eg, if the randomized clinical trial is rated high quality, its final assignment is level I). High quality should include:
    - Randomized clinical trial with greater than 80% follow-up, blinding, and appropriate randomization procedures
  - Cohort study includes greater than 80% follow-up
  - Diagnostic study includes consistently applied reference standard and blinding
  - Prevalence study is a cross-sectional study that uses a local and current random sample or censuses
  - Acceptable quality (the study does not meet requirements for high quality and weaknesses limit the confidence in the accuracy of the estimate): downgrade 1 level
    - Based on critical appraisal results
  - Low quality: the study has significant limitations that substantially limit confidence in the estimate: downgrade 2 levels
    - Based on critical appraisal results
  - Unacceptable quality: serious limitations—exclude from consideration in the guideline
    - Based on critical appraisal results

## APPENDIX H

## CRITICAL APPRAISAL SCORES

Clinical Course: Levels of Evidence Adapted From Phillips et al<sup>114</sup>

| Study                           | SR of Prospective Cohort Studies* | SR of Retrospective Cohort Studies† | Lower-Quality Retrospective Cohort Study‡ | Case Series | Expert Opinion |
|---------------------------------|-----------------------------------|-------------------------------------|-------------------------------------------|-------------|----------------|
| Frobell et al <sup>52</sup>     | X                                 |                                     |                                           |             |                |
| Katz et al <sup>78</sup>        | X                                 |                                     |                                           |             |                |
| Xu and Zhao <sup>145</sup>      |                                   | X                                   |                                           |             |                |
| Hall et al <sup>61</sup>        |                                   | X                                   |                                           |             |                |
| McLeod et al <sup>97</sup>      |                                   | X                                   |                                           |             |                |
| Østerås et al <sup>109</sup>    |                                   | X                                   |                                           |             |                |
| Al-Dadah et al <sup>3</sup>     |                                   | X                                   |                                           |             |                |
| Busija et al <sup>26</sup>      |                                   | X                                   |                                           |             |                |
| Fabricant et al <sup>48</sup>   |                                   | X                                   |                                           |             |                |
| Zaffagnini et al <sup>147</sup> |                                   | X                                   |                                           |             |                |
| Kijowski et al <sup>81</sup>    |                                   | X                                   |                                           |             |                |
| Hall et al <sup>64</sup>        |                                   | X                                   |                                           |             |                |
| Hall et al <sup>63</sup>        |                                   | X                                   |                                           |             |                |
| Hall et al <sup>62</sup>        |                                   | X                                   |                                           |             |                |
| Thorlund et al <sup>133</sup>   |                                   |                                     | X                                         |             |                |
| Thorlund et al <sup>132</sup>   |                                   |                                     | X                                         |             |                |
| Stein et al <sup>126</sup>      |                                   |                                     | X                                         |             |                |
| Scanzello et al <sup>122</sup>  |                                   |                                     | X                                         |             |                |
| Kim et al <sup>82</sup>         |                                   |                                     | X                                         |             |                |
| Goyal et al <sup>58</sup>       | X                                 |                                     |                                           |             |                |
| Goyal et al <sup>57</sup>       | X                                 |                                     |                                           |             |                |
| Campbell et al <sup>27</sup>    |                                   | X                                   |                                           |             |                |
| Filardo et al <sup>50</sup>     |                                   | X                                   |                                           |             |                |
| Harris et al <sup>65</sup>      |                                   | X                                   |                                           |             |                |
| Chalmers et al <sup>30</sup>    |                                   | X                                   |                                           |             |                |
| Howard et al <sup>70</sup>      |                                   | X                                   |                                           |             |                |
| Mithoefer et al <sup>99</sup>   |                                   | X                                   |                                           |             |                |

Abbreviation: SR, systematic review.

\*High-quality prospective cohort studies.

†Includes lower-quality prospective cohort studies, high-quality retrospective cohort studies, consecutive cohort, and outcomes studies or ecological studies.

‡Includes high-quality cross-sectional studies and case-control studies.

## Risk Factors: AMSTAR\*

| Study                             | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8  | 9 | 10 | 11 | Quality† |
|-----------------------------------|---|---|---|---|---|---|---|----|---|----|----|----------|
| Snoeker et al <sup>124</sup>      | Y | Y | Y | N | Y | Y | Y | CA | Y | CA | Y  | H        |
| Papalia et al <sup>110</sup>      | Y | Y | Y | N | N | N | Y | Y  | Y | CA | N  | A        |
| Petty and Lubowitz <sup>113</sup> | Y | N | N | Y | N | N | N | N  | Y | N  | N  | L        |

Abbreviations: A, acceptable; AMSTAR, A Measurement Tool to Assess Systematic Reviews; CA, can't access; H, high; L, low; N, no; Y, yes.

\*Yes/no. Items: 1, Was an a priori design provided? 2, Was there duplicate study selection and data extraction? 3, Was a comprehensive literature search performed? 4, Was the status of publication (ie, gray literature) used as an inclusion criterion? 5, Was a list of studies (included and excluded) provided? 6, Were the characteristics of the included studies provided? 7, Was the scientific quality of the included studies assessed and documented? 8, Was the scientific quality of the included studies used appropriately in formulating conclusions? 9, Were the methods used to combine the findings of studies appropriate? 10, Was the likelihood of publication bias assessed? 11, Was the conflict of interest included?

†What is your overall assessment of the methodological quality of this review?

## APPENDIX H

## Risk Factors: SIGN Cross-sectional\*

| Study                       | 1 | 2 | 3   | 4   | 5 | 6   | 7 | 8  | 9  | 10 | 11 | 12  | 13 | 14 | Quality <sup>†</sup> |
|-----------------------------|---|---|-----|-----|---|-----|---|----|----|----|----|-----|----|----|----------------------|
| Chhadia et al <sup>31</sup> | Y | Y | DNA | DNA |   | DNA | Y | CS | CS | Y  | CS | DNA | Y  | Y  | A                    |

Abbreviation: A, acceptable; CS, can't say; DNA, did not access; SIGN, Scottish Intercollegiate Guidelines Network; Y, yes.

\*Items: 1, The study addresses an appropriate and clearly focused question; 2, The 2 groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation; 3, The study indicates how many of the people asked to take part did so, in each of the groups being studied; 4, The likelihood that some eligible subjects might have the outcome at the time of enrollment is assessed and taken into account in the analysis; 5, What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed? 6, Comparison is made between full participants and those lost to follow-up, by exposure status; 7, The outcomes are clearly defined; 8, The assessment of outcome is made blind to exposure status (if the study is retrospective, this may not be applicable); 9, Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome; 10, The method of assessment of exposure is reliable; 11, Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable; 12, Exposure level or prognostic factor is assessed more than once; 13, The main potential confounders are identified and taken into account in the design and analysis; 14, Have confidence intervals been provided?

<sup>†</sup>How well was the study done to minimize the risk of bias or confounding?

## Risk Factors: SIGN Cohort

| Study                            | 1 | 2  | 3   | 4   | 5 | 6   | 7 | 8   | 9   | 10 | 11 | 12 | 13 | 14 | Quality <sup>†</sup> |
|----------------------------------|---|----|-----|-----|---|-----|---|-----|-----|----|----|----|----|----|----------------------|
| Pestka et al <sup>112</sup>      | Y | Y  | N   | N   |   | N   | Y | N   | Y   | Y  | Y  | Y  | N  | N  | A                    |
| Salzmann et al <sup>121</sup>    | Y | Y  | Y   | N   |   | N   | Y | DNA | N   | Y  | Y  | N  | N  | N  | A                    |
| Ebert et al <sup>42</sup>        | Y | Y  | N   | Y   |   | N   | N | DNA | CS  | Y  | Y  | N  | N  | Y  | A                    |
| Jungmann et al <sup>177</sup>    | Y | Y  | N   | N   |   | N   | Y | Y   | Y   | Y  | Y  | N  | N  | N  | A                    |
| Hwang et al <sup>171</sup>       | Y | Y  | DNA | DNA |   | N   | Y | DNA | CS  | Y  | Y  | N  | N  | Y  | A                    |
| Lyman et al <sup>94</sup>        | Y | Y  | N   | DNA |   | DNA | Y | DNA | N   | Y  | Y  | N  | Y  | Y  | A                    |
| Brambilla et al <sup>19</sup>    | Y | Y  | N   | N   |   | N   | Y | DNA | DNA | Y  | Y  | N  | Y  | Y  | A                    |
| Jaiswal et al <sup>73</sup>      | Y | Y  | N   | DNA |   | N   | Y | N   | N   | Y  | Y  | Y  | N  | Y  | A                    |
| Rosenberger et al <sup>118</sup> | Y | Y  | N   | N   |   | N   | Y | Y   | Y   | Y  | Y  | Y  | N  | Y  | A                    |
| Wu et al <sup>143</sup>          | Y | CS | Y   | Y   |   | CS  | Y | NA  | N   | Y  | Y  | N  | N  | N  | A                    |

Abbreviation: A, acceptable; CS, can't say; DNA, did not access; N, no; NA, not applicable; SIGN, Scottish Intercollegiate Guidelines Network; Y, yes.

\*Items: 1, The study addresses an appropriate and clearly focused question; 2, The 2 groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation; 3, The study indicates how many of the people asked to take part did so, in each of the groups being studied; 4, The likelihood that some eligible subjects might have the outcome at the time of enrollment is assessed and taken into account in the analysis; 5, What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed? 6, Comparison is made between full participants and those lost to follow-up, by exposure status; 7, The outcomes are clearly defined; 8, The assessment of outcome is made blind to exposure status (if the study is retrospective, this may not be applicable); 9, Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome; 10, The method of assessment of exposure is reliable; 11, Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable; 12, Exposure level or prognostic factor is assessed more than once; 13, The main potential confounders are identified and taken into account in the design and analysis; 14, Have confidence intervals been provided?

<sup>†</sup>How well was the study done to minimize the risk of bias or confounding?

## Risk Factors: SIGN Case-Control\*

| Study                          | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8  | 9 | 10 | 11 | Quality <sup>†</sup> |
|--------------------------------|---|---|---|---|---|---|---|----|---|----|----|----------------------|
| Englund et al <sup>47</sup>    | Y | Y | Y |   | Y | Y | Y | Y  | Y | Y  | N  | H                    |
| Kluczynski et al <sup>84</sup> | Y | Y | Y |   | N | Y | Y | CS | Y | N  | Y  | A                    |

Abbreviation: A, acceptable; CS, can't say; H, high; N, no; SIGN, Scottish Intercollegiate Guidelines Network; Y, yes.

\*Items: 1, The study addresses an appropriate and clearly focused question; 2, The cases and controls are taken from comparable populations; 3, The same exclusion criteria are used for both cases and controls; 4, What percentage of each group (cases and controls) participated in the study? 5, Comparison is made between participants and nonparticipants to establish their similarities or differences; 6, Cases are clearly defined and differentiated from controls; 7, It is clearly established that controls are noncases; 8, Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment; 9, Exposure status is measured in a standard, valid, and reliable way; 10, The main potential confounders are identified and taken into account in the design and analysis; 11, Confidence intervals are provided.

<sup>†</sup>How well was the study done to minimize the risk of bias or confounding?

## APPENDIX H

## Risk Factors: Modified Case Series

| Study                          | 1 | 2 | 3 | 4  | 5 | 6 | 7  | 8 | 9 | 10 | Quality <sup>†</sup> |
|--------------------------------|---|---|---|----|---|---|----|---|---|----|----------------------|
| Henry et al <sup>68</sup>      | Y | Y | Y | CS | Y | Y | CS | Y | Y | Y  | H                    |
| Crema et al <sup>35</sup>      | Y | Y | Y | CS | Y | Y | Y  | Y | Y | Y  | H                    |
| Crema et al <sup>34</sup>      | Y | Y | Y | CS | Y | Y | CS | Y | Y | Y  | H                    |
| Ding et al <sup>40</sup>       | N | Y | Y | CS | N | Y | CS | Y | Y | Y  | A                    |
| Jacob and Oommen <sup>72</sup> | N | Y | Y | CS | N | Y | CS | Y | Y | CS | A                    |

Abbreviation: A, acceptable; CS, can't say; H, high; N, no; Y, yes.

\*Items: 1, Did the study address a clearly focused question/issue? 2, Is the research method (study design) appropriate for answering the research question? 3, Are both the setting and the subjects representative with regard to the population to which the findings will be referred? 4, Is the researcher's perspective clearly described and taken into account? 5, Are the methods for collecting data clearly described? 6, Are the methods for analyzing the data likely to be valid and reliable, and are quality control measures used? 7, Was the analysis repeated by more than 1 researcher to ensure reliability? 8, Are the results credible, and if so, are they relevant for practice? 9, Are the conclusions drawn justified by the results? 10, Are the findings of the study transferable to other settings?

<sup>†</sup>How well was the study done to minimize the risk of bias or confounding?

Examination – Outcome Measures: Levels of Evidence Adapted From Phillips et al<sup>114</sup>

| Study                             | SR of Prospective Cohort Studies* | SR of Lower-Quality Prospective Cohort Studies <sup>†</sup> | High-Quality Cross-sectional Study | Lower-Quality Cross-sectional Study | Expert Opinion | Quality <sup>‡</sup> |
|-----------------------------------|-----------------------------------|-------------------------------------------------------------|------------------------------------|-------------------------------------|----------------|----------------------|
| Engelhart et al <sup>45</sup>     |                                   | X                                                           |                                    |                                     |                | A                    |
| Goodwin et al <sup>56</sup>       |                                   | X                                                           |                                    |                                     |                | A                    |
| Garratt et al <sup>54</sup>       |                                   | X                                                           |                                    |                                     |                | A                    |
| Salavati et al <sup>120</sup>     |                                   |                                                             | X                                  |                                     |                | A                    |
| van de Graaf et al <sup>136</sup> |                                   |                                                             | X                                  |                                     |                | A                    |
| Almangoush et al <sup>4</sup>     |                                   |                                                             | X                                  |                                     |                | A                    |
| Balain et al <sup>13</sup>        |                                   |                                                             | X                                  |                                     |                | A                    |
| Smith et al <sup>123</sup>        |                                   |                                                             | X                                  |                                     |                | A                    |
| Celik et al <sup>29</sup>         |                                   |                                                             | X                                  |                                     |                | A                    |
| Vaquero et al <sup>137</sup>      |                                   |                                                             | X                                  |                                     |                | A                    |

Abbreviations: A, acceptable; SR, systematic review.

\*High-quality prospective cohort study.

<sup>†</sup>Lower-quality prospective cohort study.

<sup>‡</sup>What is your overall assessment of the methodological quality of this review? (high, acceptable, low, unacceptable).

Examination – Physical Impairment Measures: Levels of Evidence Adapted From Phillips et al<sup>114</sup>

| Study                        | SR of Prospective Cohort Studies* | SR of Lower-Quality Prospective Cohort Studies <sup>†</sup> | High-Quality Cross-sectional Study | Lower-Quality Cross-sectional Study | Expert Opinion | Quality <sup>‡</sup> |
|------------------------------|-----------------------------------|-------------------------------------------------------------|------------------------------------|-------------------------------------|----------------|----------------------|
| Décary et al <sup>137</sup>  |                                   | X                                                           |                                    |                                     |                | A                    |
| Blyth et al <sup>18</sup>    |                                   | X                                                           |                                    |                                     |                | A                    |
| Haviv et al <sup>66</sup>    |                                   |                                                             | X                                  |                                     |                | A                    |
| Snoeker et al <sup>125</sup> |                                   |                                                             | X                                  |                                     |                | A                    |
| Campbell et al <sup>28</sup> |                                   |                                                             |                                    | X                                   |                | L                    |

Abbreviations: A, acceptable; L, low; SR, systematic review.

\*High-quality prospective cohort study.

<sup>†</sup>Lower-quality prospective cohort study.

<sup>‡</sup>What is your overall assessment of the methodological quality of this review? (high, acceptable, low, unacceptable).

## APPENDIX H

## Interventions: AMSTAR\*

| Study                             | 1  | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9  | 10 | 11 | Quality <sup>†</sup> |
|-----------------------------------|----|---|---|---|---|---|---|---|----|----|----|----------------------|
| Fazalare et al <sup>49</sup>      | CA | N | Y | N | N | Y | Y | Y | Y  | N  | N  | A                    |
| Papalia et al <sup>111</sup>      | CA | Y | Y | N | N | Y | Y | Y | CA | N  | N  | A                    |
| Dias et al <sup>39</sup>          | CA | Y | Y | N | Y | Y | Y | Y | Y  | N  | N  | A                    |
| Coppola and Collins <sup>33</sup> | CA | Y | Y | N | N | Y | Y | Y | CA | N  | N  | A                    |
| Reid et al <sup>116</sup>         | CA | Y | Y | N | N | Y | Y | Y | Y  | N  | N  | A                    |

Abbreviations: A, acceptable; AMSTAR, A Measurement Tool to Assess Systematic Reviews; CA, can't access; N, no; Y, yes.

\*Items: 1, The study addresses a clearly defined research question; 2, At least 2 people should select studies and extract data; 3, A comprehensive literature search is carried out; 4, The authors clearly state if or how they limited their review by publication type; 5, The included and excluded studies are listed; 6, The characteristics of the included studies are provided; 7, The scientific quality of the included studies is assessed and documented; 8, The scientific quality of the included studies is assessed appropriately; 9, Appropriate methods are used to combine the individual study findings; 10, The likelihood of publication bias is assessed; 11, Conflicts of interest are declared.

<sup>†</sup>Quality rating: 8 or higher, high; 5, 6, or 7, acceptable; 4 or less, low.

## Interventions: PEDro\*

| Study                             | 1 | 2 | 3 | 4  | 5 | 6 | 7 | 8 | 9 | 10 | 11 | Quality <sup>†</sup> |
|-----------------------------------|---|---|---|----|---|---|---|---|---|----|----|----------------------|
| Kelln et al <sup>80</sup>         | Y | Y | Y | N  | N | N | N | Y | Y | Y  | Y  | A                    |
| Edwards et al <sup>43</sup>       | Y | Y | Y | Y  | N | N | Y | Y | Y | Y  | Y  | H                    |
| Wondrasch et al <sup>141</sup>    | Y | Y | Y | CA | N | N | Y | Y | Y | Y  | Y  | H                    |
| Akkaya et al <sup>2</sup>         | N | Y | Y | Y  | N | N | Y | Y | Y | Y  | Y  | H                    |
| Lind et al <sup>90</sup>          | Y | Y | Y | CA | N | N | N | N | N | Y  | Y  | A                    |
| Katz et al <sup>78</sup>          | Y | Y | N | Y  | N | N | N | Y | Y | Y  | Y  | A                    |
| Østerås <sup>107</sup>            | Y | Y | Y | CA | N | Y | N | Y | Y | Y  | Y  | H                    |
| Østerås 2014 <sup>108</sup>       | Y | Y | N | CA | N | N | N | Y | N | Y  | Y  | A                    |
| Østerås 2014 <sup>109</sup>       | Y | Y | Y | Y  | N | Y | N | Y | Y | Y  | Y  | H                    |
| Ebert et al <sup>41</sup>         | Y | Y | N | Y  | N | N | Y | Y | Y | Y  | Y  | H                    |
| Oravitan and Avram <sup>106</sup> | Y | Y | N | Y  | N | N | N | Y | Y | Y  | Y  | A                    |
| Koutras et al <sup>86</sup>       | Y | Y | Y | Y  | Y | N | N | Y | Y | Y  | Y  | H                    |
| Kise et al <sup>83</sup>          | Y | Y | Y | CA | N | N | Y | Y | Y | Y  | Y  | H                    |
| Hall et al <sup>60</sup>          | Y | Y | Y | Y  | N | N | Y | Y | Y | Y  | Y  | H                    |

Abbreviations: A, acceptable; CA, can't access; H, high; N, no; PEDro, Physiotherapy Evidence Database; Y, yes.

\*Items: 1, Eligibility criteria were specified; 2, Subjects were randomly allocated to groups (in a crossover study, subjects were randomly allocated an order in which treatments were received); 3, Allocation was concealed; 4, The groups were similar at baseline regarding the most important prognostic indicators; 5, There was blinding of all subjects; 6, There was blinding of all therapists who administered the therapy; 7, There was blinding of all assessors who measured at least 1 key outcome; 8, Measures of at least 1 key outcome were obtained from more than 85% of the subjects initially allocated to groups; 9, All subjects for whom outcome measures were available received the treatment or control condition as allocated, or, where this was not the case, data for at least 1 key outcome were analyzed by "intention to treat"; 10, The results of between-group statistical comparisons were reported for at least 1 key outcome; 11, The study provides both point measures and measures of variability for at least 1 key outcome.

<sup>†</sup>Quality rating: 8 or higher, high; 5, 6, or 7, acceptable; 4 or less, low.

## APPENDIX H

## Interventions: Modified Case Series

| Study                           | 1 | 2 | 3  | 4  | 5 | 6  | 7  | 8 | 9 | 10 | Quality <sup>†</sup> |
|---------------------------------|---|---|----|----|---|----|----|---|---|----|----------------------|
| Wondrasch et al <sup>140</sup>  | Y | Y | Y  | CA | Y | Y  | CA | Y | Y | Y  | H                    |
| Assche et al <sup>11</sup>      | Y | Y | Y  | CA | Y | Y  | CA | Y | Y | Y  | H                    |
| Neogi et al <sup>102</sup>      | Y | Y | Y  | CA | Y | Y  | CA | Y | Y | Y  | H                    |
| Lim et al <sup>89</sup>         | Y | Y | CA | CA | N | CA | CA | Y | Y | Y  | A                    |
| Elbaz et al <sup>44</sup>       | N | Y | Y  | Y  | Y | CA | CA | Y | Y | Y  | A                    |
| Della Villa et al <sup>38</sup> | Y | Y | Y  | Y  | Y | Y  | N  | Y | Y | N  | H                    |

Abbreviation: A, acceptable; CA, can't access; H, high; N, no; Y, yes.

\*Items: 1, Did the study address a clearly focused question/issue? 2, Is the research method (study design) appropriate for answering the research question? 3, Are both the setting and the subjects representative with regard to the population to which the findings will be referred? 4, Is the researcher's perspective clearly described and taken into account? 5, Are the methods for collecting data clearly described? 6, Are the methods for analyzing the data likely to be valid and reliable, and are quality control measures used? 7, Was the analysis repeated by more than 1 researcher to ensure reliability? 8, Are the results credible, and if so, are they relevant for practice? 9, Are the conclusions drawn justified by the results? 10, Are the findings of the study transferable to other settings?

<sup>†</sup>How well was the study done to minimize the risk of bias or confounding?

# Low Back Pain: What Have Clinical Guidelines Ever Done for Us?

*J Orthop Sports Phys Ther* 2018;48(2):54-57. doi:10.2519/jospt.2018.0602

**T**he burden that low back pain (LBP) presents to sufferers and society is well established.<sup>13</sup> This ubiquitous condition is served by a complex global clinical marketplace offering a wide range of assessment alternatives and accompanying interventions. Yet, while the costs of care are rising,<sup>10</sup> the global burden does not appear to be diminishing. This speaks to the widespread delivery of ineffective or low-value interventions, some of which may be supported only by convention, marketing, survivor bias, lack of clinical reflection, or the confounders of natural history and internal study biases.

Clinical practice guidelines (CPGs) aim to bring some clarity to this confusing situation. By recommending effective evidence-based interventions and discouraging interventions lacking in scientific support, clinical guidelines seek to optimize the quality of care, while reducing the waste and the potential harm associated with ineffective or unsafe interventions. The past 3 decades have seen many guidelines published for LBP.<sup>31</sup> Indeed, the 8 months preceding the time of writing this Viewpoint have seen national clinical guidelines or updates published

in 4 nations: the United Kingdom,<sup>19</sup> the United States,<sup>6,7,23</sup> Denmark,<sup>26</sup> and Belgium.<sup>29</sup>

## Is There a Consistent Message?

With such extensive efforts, we might expect the path to good practice to be clear. Indeed, if we look for consensus across guidelines, then we can find it. This consensus should indicate a basic standard of care on which we can achieve broad agreement.

We recently contrasted 3 major CPGs for LBP,<sup>20</sup> selected on the basis of their quality, multidisciplinary nature, and relatively recent publication: the 2016 National Institute for Health and Care Excellence (NICE) guideline on low back pain and sciatica,<sup>19</sup> the 2015/2017 "Evidence-Informed Primary Care Management of Low Back Pain" (Canada),<sup>28</sup>

and the 2007, 2009, and 2017 CPG from the American College of Physicians and the American Pain Society (United States).<sup>5-9,23</sup> A narrative analysis of the recommendations of these CPGs found clear agreement on the following recommendations:

- Guidelines consistently recommend ruling out specific spinal pathology and then offering high-quality education, including the encouragement of an early return to activity
- Guidelines consistently emphasize the importance of promoting self-management
- Guidelines consistently recommend against the routine use of imaging for nonspecific LBP
- Guidelines consistently recommend physical exercise for nonspecific LBP
- Guidelines consistently advocate a cautious approach to the use of opioids in nonspecific LBP
- Guidelines consistently agree that management should incorporate assessment and management of psychosocial factors

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These recommendations should not be controversial. Indeed, simply ensuring their widespread global implementation may improve the huge burden of back pain-related disability by ensuring appropriate management and reducing overtreatment.

### Where and Why Might They Differ?

We might reasonably expect consensus across guidelines, because guideline development groups generally have access to the same evidence base. But conflicting recommendations do emerge. We can observe inconsistency in recommendations relating to the use of acupuncture, radiofrequency denervation procedures and injection therapies, and the range of drug therapies recommended.<sup>20,31</sup> Some potentially reasonable sources of variation might be related to differences in health care infrastructure and the search dates adopted by the guideline development groups. Less desirable sources of divergence might include differences in the interpretation of benefits and harms, the influence of the local political landscape, and the constitution of the guideline committee.

Guideline development groups are frequently required to synthesize information that is based on incomplete and equivocal research. In the face of uncertainty, the willingness of development groups to make positive or negative recommendations based on expert judgment is likely to vary. Marginal, inconsistent, or low-quality evidence of benefit is common and increases the potential for interpretive variation. It is telling that in the recent NICE guideline no intervention at all was considered to be supported by strong-enough evidence of benefit to warrant a clear “offer” recommendation.<sup>19</sup> Similarly, in the recent Danish guideline,<sup>26</sup> no recommendation was rated as “strong.”

The process of guideline development may itself result in variations. Guideline groups may search for evidence and perform systematic reviews and meta-analysis de novo,<sup>17</sup> rely primarily on existing

systematic reviews to inform decision making,<sup>6,7</sup> assimilate the recommendations made in previous guidelines,<sup>29</sup> or take a combination of these approaches.<sup>26</sup> While the methodologies underpinning systematic reviews may be broadly similar, the interpretation of the results by the review authors will vary. Reliance on existing systematic reviews to inform guideline recommendations naturally introduces the opinions and interpretations of the review authors into the guideline development process, and quality evaluation of those reviews is vital. Reliance on previous guideline recommendations risks presenting data that may be out of date or data that have been evaluated using outdated or suboptimal methodology.

The thresholds used for establishing efficacy or effectiveness can have an important impact. Low back pain core outcomes are subjective, trials are frequently and sometimes necessarily incompletely blinded, other more avoidable risks of bias are commonly present, and the potential for small-study effects is high. Against this backdrop, adopting thresholds of statistical significance as a surrogate marker of clinical utility becomes a very low bar to jump and can be expected to lack specificity. An alternative to statistical significance is to utilize thresholds of clinically important differences. Where clinical importance thresholds are used to inform guideline recommendations, the thresholds for clinical significance are chosen by the individual guideline groups.

To illustrate this, the NICE guideline<sup>19</sup> consistently used a threshold of 1 point on a 0-to-10 visual analog scale for rating pain intensity as part of the decision-making process. Most would consider a change of this magnitude to be a fairly low hurdle for back pain treatments to jump, yet, across that guideline, effect sizes from a range of comparisons failed to clear it. Indeed, this threshold, along with consideration of the known risks, led to a “do not use” recommendation regarding opioids for chronic LBP, despite the finding of a statistically significant difference between opioids and placebo.<sup>19</sup>

In addition to thresholds of clinical importance, the importance given to evidence of efficacy can be a source of variation. In prioritizing evidence of clinically important efficacy (versus sham) over effectiveness (versus usual care), the NICE guideline<sup>19</sup> recommended against the use of acupuncture, whereas the American College of Physicians 2017 guideline,<sup>23</sup> in which clinical significance thresholds were not set, recommended acupuncture as a first-line treatment for LBP, despite examining similar data and reaching similar conclusions regarding efficacy. This discrepancy between the outcomes of efficacy and effectiveness trials would indicate that the short-term analgesic effect seen with acupuncture is likely explained by the contextual effects of the treatment rather than by a treatment-specific effect, and raises the contentious issue of the role of known placebos in clinical care. It bears repeating that, with subjective outcomes, elaborate clinical rituals, compared to usual care, in trials of mixed quality might be predicted to show some positive effect, regardless of their specific content.<sup>2,22</sup>

There are arguments against the dismissal of very small average effect sizes. It has been suggested that for a condition with a high prevalence and burden, treatments with very small benefits may still have utility, and that small effects across large populations may shift the burden of the disease.<sup>1</sup> Very small between-group effect sizes for interventions delivered to a heterogeneous group of patients might obscure important subgroups of responders.<sup>14</sup> Outcomes in back pain trials might be bimodally distributed. In that scenario, of the patients who receive the active intervention, some experience substantial improvement, some have minimal to no change in their outcome, and very few experience intermediate improvements, leaving the mean average effect a poor reflection of treatment outcome (for more detailed discussions of this issue, see Moore et al<sup>18</sup> and O’Connell et al<sup>21</sup>). However, the costs associated with providing treatments of limited clinical

benefit to large populations may not be sustainable in many health economies. For many interventions for spinal pain, there is no current good evidence to demonstrate that outcomes are bimodally distributed,<sup>21</sup> that subgroups of patients who are likely to respond exist and can be identified, or that systems of subgrouping patients enhance clinical outcomes.<sup>16</sup>

While there are a number of reasons for variation between guidelines, the potential for divergence decreases when the volume and quality of evidence increase and there is clear evidence of clinically important benefit. There is a good case to be made that inconsistency of recommendations across guidelines is a warning sign of evidential thin ice for those interventions. An intervention backed by only some guidelines might carry a “buyer beware” label.

## The Challenge of Changing Practice

What is the point of the guideline that nobody follows? Simply publishing a guideline is clearly not enough to improve care,<sup>4,30</sup> but how to achieve effective implementation is an open question. The goal is to achieve lasting behavioral change in complex communities of clinicians, including the de-adoption of some current practices. A recent systematic review of implementation strategies indicated that single, one-off education strategies were consistently unsuccessful,<sup>17</sup> but the evidence for the effectiveness of multifaceted implementation strategies is also not compelling.<sup>27</sup>

But why should implementation be so difficult? There are multiple barriers at play.<sup>12</sup> These include clinicians’ knowledge and understanding of the guideline, their willingness to accept its recommendations (often in the face of deeply held beliefs, clinical experience, and vested interests), issues related to the feasibility of implementing the recommendations within local clinical structures, the accessibility and credibility of the guideline itself,<sup>3,4,11,24</sup> and the acceptability, or lack thereof, of the guideline recommendations to patients.<sup>25</sup>

This might give us pause for reflection. What factors are really driving a reluctance to change or to de-adapt our favored practices? Arguments against change are often framed in terms of maintaining patient choice, but there is always the danger of conflating what is good for our patients with what is good for ourselves and our profession(s). Another common response is to retreat into uncertainty. This approach is not inherently unreasonable, given the frequently immature evidence base and the proposed limitations of clinical trials in terms of adequately reflecting the heterogeneity of back pain.<sup>14</sup> But in the end, the burden of proof should lie with the advocates of interventions. The failure of many popular interventions to meet a reasonable threshold of evidence prompts us to consider how we ended up routinely advocating and delivering treatments based on uncertain clinical benefit. If evidence-based practice is the goal, then it does not seem reasonable to recommend interventions for which the evidence base is currently missing or discouraging, despite advocacy or patient demand. It should offer some comfort that, as the evidence base evolves, we can expect updated guideline recommendations to reflect that change, and there remains some possibility that future evidence may support interventions that cannot currently be recommended. But for interventions with a more mature evidence base, this seems unlikely.

## What Have Clinical Guidelines Ever Done for Us?

Considerable effort internationally has gone into developing CPGs for LBP. So, to paraphrase Monty Python,<sup>15</sup> “What have clinical guidelines ever done for us?”

They may not offer simple and guaranteed options for this complex condition, but they do offer us some clear targets for reducing waste and harm, and they promote the delivery of good information to patients, self-management, and a shift toward a less interventionist culture in clinical management. Guidelines also highlight the considerable work yet to be

done to optimize care. The ultimate goal of a CPG is to positively influence health outcomes. This requires policy makers and health systems to invest in their use, and clinicians to ensure that best-practice guidance is used productively, in collaboration with the patient, to inform treatment decision making. ●

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# Entrapment Neuropathies: Challenging Common Beliefs With Novel Evidence

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**E**ntrapment neuropathies are the most prevalent type of peripheral neuropathy and often a challenge to diagnose and treat. To a large extent, our current knowledge is based on empirical concepts and early (often biomechanical) studies. This Viewpoint will challenge some of the current beliefs with recent advances in both basic and clinical neurosciences.

## Extradermatomal/Extraterritorial Symptoms Are Common in Entrapment Neuropathies

Classical textbooks describe that symptoms in patients with entrapment neuropathies follow defined anatomical distributions (eg, dermatome, peripheral innervation territory). However, up to two thirds of patients present with symptoms that do not correlate with defined distributions.<sup>10,27</sup> This may be explained by the large variability and significant overlap of dermatomes/innervation territories, as well as by symptoms originating from deeper structures (eg, myotomes, sclerotomes), which may not coincide with superficial innervation territories. These mechanisms, however, cannot account for extensive spread of symptoms as described by many patients. For instance, patients with carpal tunnel syn-

drome (CTS) often report symptoms in a glove distribution, as well as proximal spread into the arm.<sup>29</sup>

Recent data suggest a contribution of remote immune-inflammatory mechanisms to extraterritorial symptom spread. In our experimental model, mild chronic sciatic nerve compression induced an immune-inflammatory response at the level of the dorsal root ganglia, far away from the site of the sciatic nerve lesion.<sup>37</sup> It is well established that neurons lower their firing threshold if exposed to an inflammatory environment, leading to neuropathic pain behavior.<sup>46</sup> Because the dorsal root ganglia contain thousands of neuronal cell bodies originating from sites distant to the original injury, a general decrease in firing threshold can explain the spread of symptoms outside the territory of the affected nerve.

In addition, severe nerve injuries may induce a neuroinflammatory reaction with activation of glial cells at the level of the spinal cord<sup>21</sup> or higher pain centers.<sup>26</sup> This immune-inflammatory response may spread to contralateral dorsal root ganglia or dorsal horns of the spinal cord,<sup>20</sup> which may account for mirror pain. It could be speculated that bilateral carpal tunnel symptoms, which often disappear following unilateral surgery,<sup>51</sup> may be attributed to such contralateral immune-inflammatory mechanisms.

In summary, symptoms that do not follow a clearly defined dermatomal/peripheral innervation pattern do not rule out an entrapment neuropathy. Rather, extraterritorial spread occurs in the majority of patients.<sup>10,27</sup>

## Reliance on Large-Fiber Tests Is Insufficient to Diagnose Patients With Entrapment Neuropathies

The core sign of neural damage is loss of function, which can be examined with a standard clinical neurological examination (light touch, reflexes, muscle strength) and electrodiagnostic studies.

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Abnormalities in these tests are often considered as the gold standard for diagnosing entrapment neuropathies. However, these tests may be normal in some patients (eg, approximately 25% of patients with CTS), even though the reported symptoms are strongly indicative of a neural involvement.<sup>50</sup>

To understand this discrepancy, it is important to remember that the above-mentioned clinical neurological and electrodiagnostic tests exclusively examine large myelinated fibers (eg, A- $\beta$  and motor fibers), which only make up approximately 20% of a peripheral nerve. This clinical reliance on large fiber tests stems from early animal experiments demonstrating that acute and severe nerve injuries predominantly cause degeneration of the large fiber population,<sup>2</sup> whereas unmyelinated fiber conduction seems relatively resistant to acute nerve compression.<sup>12</sup> Recent work looking at slowly progressive, mild nerve compression, which more closely mimics entrapment neuropathies, suggests that there is preferential degeneration of small fibers, whereas myelinated axons show signs of demyelination but remain largely intact.<sup>37</sup> Data in patients with entrapment neuropathies have confirmed that early small fiber degeneration (evidenced by reduced innervation density in skin biopsies) and dysfunction (eg, altered thermal detection thresholds) precede changes in large fiber function.<sup>35,43</sup> These findings suggest that relying solely on large fiber tests in clinical practice may not be sufficient to assess patients with suspected entrapment neuropathies.

Clinically, the function of small sensory fibers can be tested with quantitative sensory testing using thermal thresholds or the ability to perceive sharp pinprick sensations. There is growing evidence that small fiber dysfunction is common in patients with both distal (eg, CTS) and proximal (eg, radiculopathies) entrapment neuropathies.<sup>39,45</sup> Though quantitative sensory testing has the advantage of determining thresholds in a validated and standardized manner, the equipment

can be too costly for clinical settings. The use of a cluster of simple clinical tests, such as neurotips for pinprick sensation and warm and cold coins for thermal thresholds, may be an inexpensive and valid option for diagnosing small fiber degeneration.<sup>31</sup>

### Value and Pitfalls of Neurodynamic Tests

Neurodynamic tests were first described in the late 19th century<sup>42</sup> and introduced into physiotherapeutic practice following the pioneering work of Bob Elvey, David Butler, and Michael Shacklock. The original terms, such as *brachial plexus tension test*, *upper-limb tension test*, and *adverse mechanical tension*, suggest that the underlying neural disorders were due to abnormal tension. However, this view has changed over time, in that the tests are not tests of tension but, rather, examine neural mechanosensitivity. Thus, the nomenclature was adjusted to *neural tissue provocation tests* or *neurodynamic tests*. Unfortunately, the nomenclature is still not used uniformly, leading to misconceptions in the medical field.

Neurodynamic tests are part of a standard clinical examination, but the interpretation of these tests and what constitutes a positive test vary greatly in the literature. While some define a positive response as the reproduction of the patient's symptoms together with reduced range of motion in the symptomatic limb compared to the asymptomatic side, it has recently been suggested that partial reproduction of symptoms and structural differentiation are essential criteria for a positive test.<sup>28</sup> Certainly, sensitizing maneuvers are crucial for differentiating nerve-related mechanosensitivity from other soft tissue-related mechanosensitivities. Furthermore, pain responses to specific neurodynamic tests should correlate with pain responses on respective active limb movements,<sup>19</sup> as both movements induce strain and excursion of the affected nerve structure.

The interpretation of neurodynamic tests can be challenging. Historically, neurodynamic tests were thought to be

diagnostic for entrapment neuropathies and are still frequently used for this purpose in clinical and research settings. An increasing body of literature suggests, however, that these tests in isolation have limited diagnostic performance.<sup>49</sup> Indeed, a significant percentage of patients with confirmed entrapment neuropathies present with negative neurodynamic tests.<sup>3</sup> The explanation for this phenomenon is that neurodynamic tests are tools to assess gain of function, that is, hypersensitivity to a mechanical stimulus, and do not assess loss of function, which is the predominant feature in some patients with entrapment neuropathies.<sup>35,45</sup> Of note, recent studies suggest that those patients with more severe loss of nerve fiber function are less likely to show signs of heightened nerve mechanosensitivity.<sup>3,8</sup> These findings indicate that negative neurodynamic tests do not exclude the presence of nerve dysfunction. It is also important to note that exaggerated responses on neurodynamic testing do not necessarily imply sensitization of peripheral nervous tissues, but can be attributed to widespread or generalized hypersensitivity, as demonstrated by bilateral pain responses on neurodynamic testing in patients with whiplash-associated disorders<sup>41</sup> and fibromyalgia.<sup>44</sup> Therefore, test responses should always be interpreted within the framework of a comprehensive clinical examination and sound reasoning. The skillful use of tests for heightened nerve mechanosensitivity and their careful interpretation remain important, as targeted treatment can improve patient outcome.<sup>34</sup>

Another misconception is that signs of heightened nerve mechanosensitivity imply the presence of neuropathic pain. Under the former definition of neuropathic pain, that is, "pain caused by a primary lesion or dysfunction of the nervous system," one could interpret noncompliance to movement as a dysfunction of the nervous system. However, the new definition, "pain caused by a lesion or disease of the somatosensory system,"<sup>22</sup>

refers to the presence of nerve damage. Numerous experimental and clinical studies<sup>1,7,14,48</sup> have demonstrated that features of heightened nerve mechanosensitivity can be present in the absence of any nerve damage, hence in the absence of neuropathic pain. In this case, the underlying pain is classified as nociceptive pain,<sup>24</sup> which is possibly initiated by activation of nociceptors within the connective tissue of the peripheral nerve (nervi nervorum). However, heightened neural mechanosensitivity can also coexist with signs of nerve damage and associated neuropathic pain.<sup>45</sup>

## Neurodynamic Treatments: Beyond Biomechanical Effects

Neurodynamic treatments are commonly used in the management of entrapment neuropathies, with proven benefits for nerve-related neck/arm and back/leg pain.<sup>4</sup> The rationale behind neurodynamic treatments has largely been based on biomechanical principles. Indeed, several cadaver and in vivo studies support the notion that neurodynamic techniques, and “sliders” in particular, are capable of inducing longitudinal movement of neural tissues in relation to their surrounding structures.<sup>11</sup> This biomechanical effect seems to be desirable to address the reduced nerve excursion that is observed in patients with CTS.<sup>15</sup> However, similar reductions in nerve excursion in other entrapment neuropathies have either not been studied or not been confirmed.<sup>30</sup> To our knowledge, no study to date reports changes in nerve gliding following neurodynamic interventions in patients with entrapment neuropathies. Of note, though carpal tunnel surgery does not alter neural excursion, symptoms subside.<sup>47</sup> One could thus argue that biomechanical factors are unlikely to account for symptoms and, therefore, may not be the main targets of nonsurgical management.

Recent advances in neuroscience have suggested potent neurophysiological effects of neurodynamic treatments. These treatments can induce immediate (but mostly short-lasting) hypoalgesia in hu-

mans,<sup>5,6</sup> and may contribute to the dispersal of intraneural edema.<sup>9,18,38</sup> Animal studies revealed that neural mobilization may induce anti-inflammatory effects beyond the lesion site, including within the dorsal root ganglia<sup>33</sup> and higher pain centers.<sup>17</sup> Furthermore, these techniques may activate endogenous opioid analgesic pathways in the midbrain<sup>32</sup> and facilitate peripheral nerve regeneration.<sup>13</sup> These experimental data supporting neurophysiological effects are encouraging, but further research is required to confirm these findings and to establish potential dose-dependent effects of neural mobilizations.

## Management: Treating Peripheral or Central Mechanisms?

In patients with entrapment neuropathies, as in many other musculoskeletal conditions, the contribution of central mechanisms has gained increasing interest in the past decade. Indeed, patients show signs of widespread hyperalgesia,<sup>16,52</sup> altered conditioned pain modulation,<sup>40</sup> as well as structural and functional (sub)cortical changes.<sup>23,36</sup> These findings are suggestive of central mechanisms, such as central sensitization, changes in descending inhibition/facilitation, or remote neuroinflammation.

Central sensitization is thought to be the cause of persistent pain where peripheral triggers are absent (or not detectable with our current medical technology). In patients with entrapment neuropathies, however, peripheral afferent barrage continues to be abnormal (too much and/or too little), which will undeniably perpetuate central adaptations. The importance of the peripheral trigger in entrapment neuropathies is well established: there is often immediate relief of focal and widespread symptoms following decompression surgery or steroid injections,<sup>25</sup> even after long-standing symptoms. These findings highlight that the treatment of the peripheral trigger—if identifiable and responsive to management—is crucial, even when patients show signs of central

contributions. Nevertheless, the scientific evidence for nonsurgical management to address the peripheral and central mechanisms in patients with entrapment neuropathies remains sparse, and future research is required to evaluate the most effective treatment strategies.

## Take-Home Message

In light of the emerging evidence, we recommend that clinicians consider the following when assessing and treating patients with entrapment neuropathies:

- Nondermatomal/territorial distribution of symptoms is the norm and not the exception, and certainly does not exclude the presence of an entrapment neuropathy
- Specific tests for the small fiber population should be included in the standard clinical neurological examination
- Neurodynamic tests are not diagnostic for entrapment neuropathies, but detect heightened neural mechanosensitivity
- Negative neurodynamic tests do not exclude nerve dysfunction
- Signs of heightened nerve mechanosensitivity do not imply the presence of neuropathic pain
- The effects of neurodynamic treatment may extend well beyond biomechanical mechanisms
- Treatment of the peripheral trigger, if identifiable and responsive to treatment, remains an integral part of management, even when central mechanisms are present

The scientific evidence surrounding neural pathology has increased exponentially over the past decade, and future research will further challenge our understanding of entrapment neuropathies. Undoubtedly, a comprehensive scientific approach, including both basic as well as clinical studies, is required to improve our understanding of the pathomechanisms, assessment tools and their interpretation, as well as optimal management options for patients with entrapment neuropathies. ●

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