

# A valid and reliable clinical outcome measure for patellofemoral instability

Patellofemoral instability can be an extremely debilitating and painful condition. Recognising that the previous outcome measures used to assess patients after treatment were not ideal for patellofemoral instability, Dr Laurie Hiemstra, based at Banff Sport Medicine in Alberta, Canada, designed a new assessment questionnaire specifically for these patients. After testing and researching an initial version, the research team completed further analysis resulting in the Banff Patellofemoral Instability Instrument (BPfII) 2.0. The 23 questions in the BPfII 2.0 assess patients' quality of life after injury and treatment.

In a normal knee, the patella (otherwise known as kneecap) rests inside the trochlea, a groove at the bottom of the femur (or thigh bone). You can think about this as if the groove is a train track and the patella is the train. As the knee bends and straightens during activities, the kneecap slides up and down, but stays in the groove. However, any situation where the patella comes out of the trochlea (or off the track) and dislocates, can be extremely painful. This condition is known as patellofemoral instability and can be challenging to treat.

For many years, patellofemoral instability has been the focus of research for Dr Laurie Hiemstra and her team, based at Banff Sport Medicine, Alberta, Canada. Historically, this condition was grouped together with other knee injuries. However, including a wide range of knee

conditions in the same group led to confusion when trying to decide the best treatments to use, or how to assess outcomes following treatment.

Concerned by the lack of an appropriate outcome measure to assess patients with patellofemoral instability, Dr Hiemstra developed a new disease-specific assessment method, purposely designed for this condition. Crucially, the questionnaire is specific to patellofemoral instability, to enable assessment of the wide range of presentations as well as the outcome of various treatments.

## PATELLOFEMORAL INSTABILITY

Patellofemoral instability can have many different presentations and is most common amongst 15 to 19 year olds. In some patients an injury, such as a direct hit to the knee for example, can force the patella out of the trochlear groove. In other cases, variations in a patient's anatomy might allow the patella to dislocate with minimal force. In either case, patients are likely to experience a significant decrease in function, as well as pain, weakness, limited range of motion and, in the long term, an increased risk of osteoarthritis.

More than half of the patients that suffer patellofemoral instability once, will go on to experience ongoing episodes. These repeat injuries make returning to normal activities quite challenging, particularly for athletes and physically active patients. In fact, after the first dislocation episode, more than half of all patients feel they're not strong or stable enough to return to their pre-injury fitness and recreation activities. Treating this condition is complex, with many different techniques and approaches used for the varying presentations of patellofemoral instability.



Knee joint showing the patella (kneecap) that articulates at the bottom of the femur (thigh bone).



Dr Hiemstra developed a specific outcome measure to assess patients with patellofemoral instability.

## ASSESSING PATIENTS

Assessing patients to understand if a treatment worked for them is typically completed using questionnaires. These questionnaires, known as patient-reported outcome measures (PROM), have become increasingly important over the past two decades for evaluating treatment outcomes. PROMs can assess the physical aspects of a condition including symptoms like pain and strength but can also range across broader topics to assess a patient's quality of life, including physical symptoms, ability to perform normal daily activities, recreation and sport activities, and psychological or emotional concerns.

Researching patellofemoral instability treatments was previously challenging because none of the available PROMs used to assess patients were designed for this particular condition. The Kujala score, for example, a 13-item questionnaire developed in 1993 for anterior knee pain, includes only one question specific to patellar instability even though it is frequently used as a PROM for patellofemoral instability. The Norwich Patellar Instability (NPI) score, a 19-item questionnaire, is a newer disease-specific PROM with a focus on assessing only physical symptoms.

"These outcome measures evaluate patellofemoral pain, patellofemoral dysfunction, or activity levels, but none is sufficiently comprehensive for the assessment of quality of life in patients with patellofemoral instability," explains Dr Hiemstra.

To address the need for a holistic and disease-specific PROM, the initial iteration of the Banff Patellar Instability Instrument (BPfII) was published in 2013. Developed by Dr Hiemstra and her team, the questionnaire contained 32 items, assessing various aspects linked

An important step for the BPfII to be accepted by the medical community was to demonstrate how the questionnaire development process addressed the criteria from the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN).

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with quality of life, including symptoms and physical complaints (5 items), work-related concerns (4 items), recreational activity and sport participation or competition (12 items), lifestyle (6 items), and social and emotional (5 items). By including these distinct domains, the BPfII was designed to capture the overall quality of life of patients with patellofemoral instability.

The BPfII is a self-administered questionnaire, which in practical terms means that the patient assesses their own health, without interpretation or input from doctors or other healthcare providers. To complete the BPfII, patients mark their response on a line measuring 100mm in length. Each answer carries the same weighting, with the final score an average of all answered questions. A higher score reflects a higher quality of life.

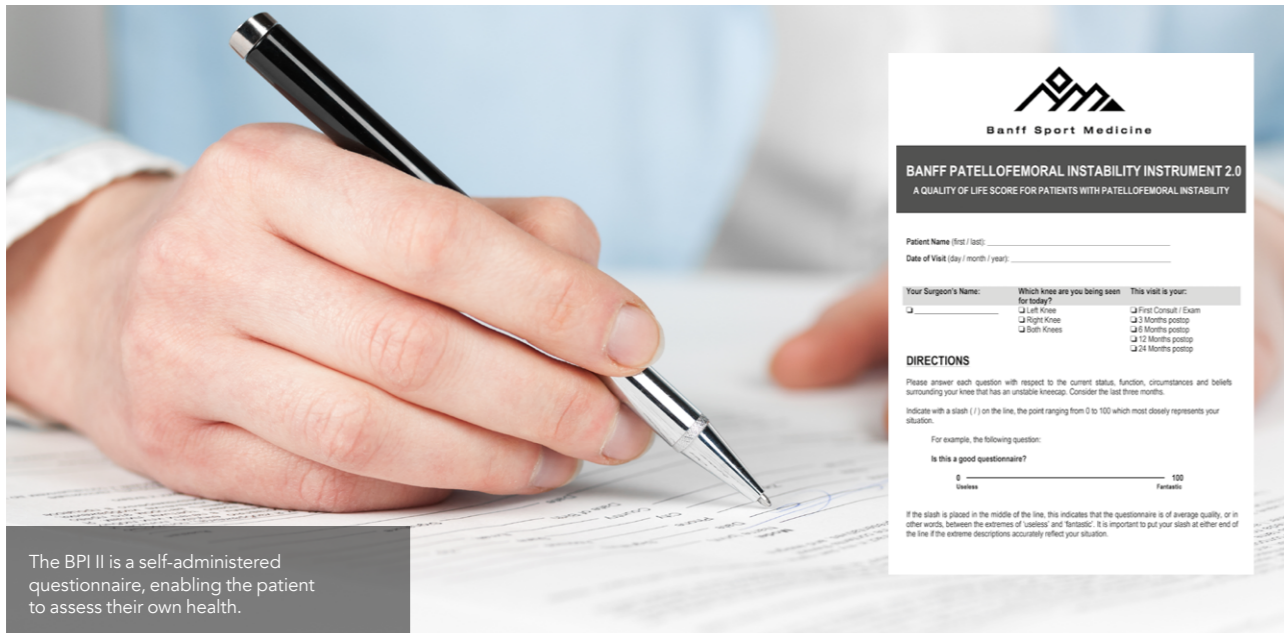
COSMIN has established checklists and procedures to test the quality of different PROMs used for research and clinical practice.

Dr Hiemstra's team progressively completed research of the BPfII consistent with the COSMIN guidelines. Through this research, the BPfII was shown to be valid, reliable and responsive for patients with recurrent patellofemoral instability as well as after stabilisation surgery. The BPfII was sensitive to detect differences in outcome scores between the initial consultation before treatment and at 6- and 12-months after surgery.

Despite these strong initial research findings, the team noticed that some patients were unable to answer all the questions. For example, young patients struggled with questions about returning



Patellofemoral instability can be extremely painful and challenging to treat.



The BPII is a self-administered questionnaire, enabling the patient to assess their own health.

to work, while patients not involved in sport found these questions difficult to answer. When patients were engaged in exploratory interviews about the BPII questionnaire, some also commented that it was too long and that some questions were redundant.

#### INTRODUCING BPII 2.0

Based on the progressive BPII research, Dr Hiemstra and her team completed a factor analysis and item reduction with the development of a new shorter and more specific questionnaire: the BPII 2.0. The new BPII version maintained the same quality of life domains but was reduced to 23 questions. The most significant difference between BPII and BPII 2.0 was the wording used in each question. For example, to be more inclusive with young patients, all questions about 'work' were adjusted to ask about 'work and/or school.' Along the same lines, 'sport' was replaced with 'recreation/sport/activity' in an attempt to cover the physical activity of patients more comprehensively.

After completing the BPII 2.0, the team successfully demonstrated equivalence between the BPII and BPII 2.0. "It was extremely important that the original BPII correlate significantly with the BPII 2.0," says Dr Hiemstra, "to allow for interchangeability between the original and the newer measure."

The BPII 2.0 has already been translated from English into other languages and the validated German version is

## The BPII was sensitive to detect differences in outcome score between the initial consultation before treatment and 6-month and 12-months post-treatment or after surgery.

currently being used in Germany, Austria, and Switzerland. Further validation of translated versions is underway for Dutch, Swedish, Spanish, Portuguese, Finnish, and French.

#### PAEDIATRIC VERSION

Another challenge with a PROM is the grade level of language used. This is particularly relevant for younger patients, who may experience difficulties fully understanding the questions or instructions for completion. Dr Hiemstra explains: "Paediatric patients have unique functional considerations as well as abilities to understand questions used in outcome tools. Therefore, an adult PROM may not be appropriate for use with younger patients, and tools validated for use in paediatric patients should be selected whenever possible."

Keen to expand the use of the BPII 2.0, the research team tested the validity and reliability of the questionnaire with a group of adolescents. In individual interviews conducted after completion of the questionnaire, all patients mentioned that they found the questions easy to read

and that the information was relevant to them. The BPII 2.0 is currently the only disease-specific PROM for patellofemoral instability tested and validated for young patients.

#### TAKING THE TOOL FORWARD

The BPII 2.0 is a holistic PROM that provides patients with an opportunity to evaluate if the treatment of their condition was effective and improved their overall quality of life. In contrast, other questionnaires (including generic knee outcome measures, activity assessment measures, and/or psychological outcome measures) may not identify the nuances of a specific disease or condition, and may be either too broad or too narrow to provide an accurate overall outcome of treatment for patellofemoral instability. The research team advocates the use of a combination of PROM tools to provide a well-rounded evaluation of treatment outcomes. "Combining a score such as the BPII 2.0 with other measures that are knee or symptom-specific," concludes Dr Hiemstra, "may provide a more complete picture of patient outcomes."

# Behind the Research



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## Research Objectives

Banff Sport Medicine is a team of health care professionals whose goal is to provide world class care in sport-related musculoskeletal trauma and reconstructive surgery.

## Detail

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#### Bio

Laurie A Hiemstra, MD, PhD, FRCSC is a sport medicine and arthroscopy orthopaedic surgeon working in Banff, Canada. She specialises in tertiary knee ligament surgery with a special interest in patellofemoral instability.

Sarah Kerslake, MSc, BPhy is director of research at the Banff Sport Medicine Foundation. She has an interest in outcomes following knee ligament injury, including optimal rehabilitation and patient-reported assessments.

Mark Lafave, PhD, CAT(C) is a professor in the Athletic Therapy program at Mount Royal University Calgary, Canada. His research extends across multiple disciplines with a strong interest in the field of measurement and evaluation.

#### Funding

Unrestricted and in-kind research support from Conmed Canada and LifeMark Health Canada has been used to facilitate the development of this patient-reported outcome measure (PROM) and associated research.

#### Collaborators

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- Gregory M. Buchko
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## Personal Response

**Are there any further tests to have the BPII 2.0 fully accepted by COSMIN standards?**

Further work on the BPII 2.0 will include establishing normative data in patients with no knee injury. Ongoing hypothesis testing will confirm the utility of the BPII 2.0 in comparing different treatment options. Establishing the minimally important clinical difference will help define the amount of change in that score that is significant for assessment of individual outcomes as well as when comparing groups. Finally, translation into a greater range of languages will allow the sharing of outcomes data and studies around the world.