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 (BPII) 2.0. The 23 questions in the BPII 2.0 assess patients’ quality of life after injury and treatment.

Patellofemoral instability can be extremely painful and challenging to treat.

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.

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.

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.

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.

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.

To address the need for a holistic and disease-specific PROM, the initial iteration of the Banff Patellar Instability Instrument (BPII) was published in 2013. Developed by Dr Hiemstra and her team, the questionnaire contained 32 items, assessing various aspects linked 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 (9 items), and social and emotional (5 items). By including these distinct domains, the BPII was designed to capture the overall quality of life of patients with patellofemoral instability.

The BPII 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 BPII, patients mark their findings, the team noticed that some respondents found the questionnaire too long. To address this, the team progressively completed research of the BPII consistent with the COSMIN guidelines. Through this research, the BPII was shown to be valid, reliable and responsive for patients with recurrent patellofemoral instability as well as after stabilisation surgery. The BPII 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...
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. 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 correlates 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 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.”

Kean 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.”

The validation of the German version is ongoing, in order to allow a wider use of the questionnaire for use in paediatric patients. The validated German version is from English into other languages and the validated German version is 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 minimal clinically important 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 for assessment of individual outcomes as well as when comparing groups.