Conversion of the Knee Osteoarthritis Outcome Score – Physical Shortform into a Video Format

by

Jordy Anterio de Roos

BSc (Hons) Biokinetics/Sport & Exercise Science

DRSJOR001

This study is in fulfilment of the requirements for the degree

Master of Science (Med) in Sports Injuries

University of Cape Town

Supervisor(s): Dr Michael Held, Dr Neil Kruger

March 2018

DECLARATION

I, Jordy de Roos, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever. I further declare the following:

1. I know that plagiarism is a serious form of academic dishonesty.
2. I have read the document about avoiding plagiarism, am familiar with its contents and have avoided all forms of plagiarism mentioned there.
3. Where I have used the words of others, I have indicated this by the use of quotation marks.
4. I have referenced all quotations and properly acknowledged other ideas borrowed from others.
5. I have not and shall not allow others to plagiarise my work.
6. I declare that this is my own work.
7. I am attaching the summary of the Turnitin match overview.

Signature: …. Signed by candidate**… Date: ……07/01/2018……**

ABSTRACT

Introduction Patient Reported Outcome Measures (PROMs) are an integral part of evidence-based medicine and provide the necessary information for clinicians to make decisions in patient management. The Knee Osteoarthritis Outcome Score-Physical Function Short Form (KOOS-PS) was developed to assess patients' perception of their knee's function. Yet, there are cultural and language barriers, when implementing PROMs in a setting for which it was not originally designed, particularly in low-middle income countries with low levels of education. To address these challenges, the study introduces a video version of the KOOS-PS with the aim to validate it in a local setting.

Methods This is a validation study of a video version of the KOOS-PS against various other knee scores. The KOOS-PS was converted into videos and a Likert scale in form of icons was used as grading system. The videos were reviewed by a panel for acceptance and comprehensibility. Second, the video score was tested in a prospective study against other internationally accepted and validated knee PROMs. Patients were recruited from both the public and private sectors of healthcare. Descriptive statistics, Pearson's correlation coefficient and Cronbach's Alpha were used for psychometric testing.

Results The mean time taken to complete the video score was 79 seconds. Internal consistency received an excellent Cronbach's Alpha of 0.89. Reproducibility received a Pearson Correlation Coefficient of r=0.91 which illustrates there was no significant difference. Pearson Correlation coefficients between the converted video score and other validated scores indicated high correlation.

Conclusion This is the first validation study that converts a written PROM into a video format. The results show that the video score is reliable, acceptable, and valid, and can therefore be used in clinical practice.

ACKNOWLEDGEMENTS

The below mentioned people have played an integral role in this thesis. They deserve to be acknowledged and thanked for their contributions.

Dr Michael Held, who provided the research idea and offered to get me on the program and obtain an MSc. He has helped me conquer tasks that I was not originally comfortable with and taught me a great deal with his experience as an academic.

Dr Neil Kruger, who as a co-author, guided me through the process of analysing my data and strategically appraising literature. His patience, understanding, and willingness to help cannot be overlooked.

Juan Kloppers, for assisting with the statistical analysis of the collected data. Thank you for your efficiency.

Penny Stopford, as an academic in psychology, who used her knowledge and experience to assist with proofreading and editing.

Table of Contents

List of tables and figures 7
- **Figures** 7
- **Tables** 7

Abbreviations 8

Introduction to the thesis 9

Chapter 1: Background and Literature Review 10
- **Objectives** 10
- **Literature research strategy** 10
- **Background** 10
- **Impact of knee injury on Health-Related Quality of Life** 11
- **Commonly used Knee-Specific PROMs** 11
  - Oxford Knee Score (OKS) 11
  - Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC) 12
  - The Knee Osteoarthritis Outcome Score (KOOS) and its Physical Function Shortform (KOOS-PS) 12
- **Implementation of PROMs** 13
- **Language and Cultural Barriers** 14
- **Quality Criteria for a Patient Reported Outcome Measure** 15

Table 1. The COSMIN Checklist: 10 Measurement properties. 16
- **Research gap** 16
- **Research Aims, Questions and Hypotheses** 17
  - Aim 17
  - Research Question 17
  - Research Hypothesis 17

Chapter 2: Methods 18
- **Converting the KOOS score into a video** 18
- **Patient Recruitment** 19
  - Inclusion and Exclusion Criteria 19
- **Reliability** 20
- **Validity** 20
- **Comprehensibility and acceptance** 21
- **Ethical Compliance** 21

Chapter 3: Results 23
- **Patient Demographics** 23
- **Reliability** 25
- **Validity** 26
- **Comprehensibility, Acceptance and Time** 27

Chapter 4: Discussion 28
- **Patient demographics and characteristics** 28
- **Validity and reliability** 28
- **Acceptance** 29

Limitations 29
Chapter 5: Conclusion 31
References 32
Appendices 42
Questionnaires and Data Capture Instruments 42
The KOOS-PS 45
Oxford Knee Score 46
WOMAC 49
Consent Forms and Patient Information 50
Research Protocol 52
DRC and HREC Approval 64

LIST OF TABLES AND FIGURES

Figures

Figure 1. The original validation process of the KOOS. 15
Figure 2. Likert scale in form of smileys. 19
Figure 3. Patient inclusion diagram. 23
Figure 4. Patient Pathology Groups. 25
Figure 5. Bland and Altman Plot for the Video score vs Written KOOS-PS. SD=Standard Deviation. 26

Tables

Table 1. The COSMIN Checklist: 10 Measurement properties. 16
Table 2. Rating scale of the Pearson r Correlation 21
Table 3. Patient Descriptive Statistics. 24
Table 4. Reliability of the Video Score. 25
Table 5. Correlation between the Video Score and the OKS, WOMAC, and KOOS-PS. 26
Table 6. Mean Time (seconds) of 43 Patients to Complete Questionnaires. 27

ABBREVIATIONS

ACL – Anterior Crutiate Ligament

ADL – Activities of Daily Living

COSMIN – Consensus-based Standards for the selection of health status Measurement Instruments

GBD – Global Burden of Diseases

HPCSA – Health Professions Council of South Africa

HRQoL – Health Related Quality of Health

KOOS – Knee Osteoarthritis Outcome Score

KOOS-PS – Knee Osteoarthritis Outcome Score – Physical Shortform

OA – Osteoarthritis

OKS – Oxford Knee Score

OMERACT – Outcome Measures in Rheumatology

PROM – Patient Reported Outcome Measure

PROS – Patient Reported Outcome Score

SD – Standard Deviation

SF-12 – Shortform 12 General Health Questionnaire

TKA – Total Knee Arthroplasty

WOMAC – Western Ontario & McMaster Universities Osteoarthritis Index

INTRODUCTION TO THE THESIS

This thesis describes how the Knee Osteoarthritis Outcome Score-Physical Shortform (KOOS-PS) was converted into a video format and validated against other knee scores. Chapter 1 is the background and literature review on Patient Reported Outcome Measures (PROMs) used in Orthopaedic surgery. This chapter covers the objectives, the search strategy, introduces the PROMs used, and mentions the research gap in the study. Chapter 2 is the methods of the study. It provides the protocol followed in the design and validation process of the video score. This chapter had two sections, the conversion of the KOOS-PS into videos, and then it was tested on a clinical cohort for validation. Chapter 3 is the results of the study. This chapter reports on the patient demographics, reliability, validity and acceptance of the study. Chapter 4 is the discussion. This chapter elaborates on the patient demographic in more depth, discusses the results and compares it to other literature. Study limitations are also identified in this chapter. Chapter 5 covers the conclusion reached in the study which is that the score is reliable and valid for use in clinical practice in Cape Town, South Africa. The Appendices contains the data collection instruments which includes both versions of the video score, the other written scores used and the necessary forms used in the data collection process. The research protocol, along with its approval letters from the Human Research Ethics Committee (HREC) and Departmental Research Committee (DRC) are also added in the appendix.

CHAPTER 1: BACKGROUND AND LITERATURE REVIEW

Objectives

This chapter will provide an introduction and overview of the relevant literature. It will introduce Patient Reported Outcome Measures (PROMs) and their use in orthopaedic surgery and knee surgery. It will also discuss the language and cultural barriers in the utilisation of PROMs and methods to overcome these. It will provide an overview of the quality criteria in validating PROMs and explore possible methods to improve the utilisation of PROMs in practice, especially through visual media in healthcare. After highlighting the research gap, the aims, questions, and hypotheses of this thesis will be discussed.

Literature research strategy

The literature search was performed in the PubMed and Google Scholar database. The initial search was performed in March 2016, with cross-checking of reference lists for inclusion. Search terms included the following: patient reported outcome score, patient reported outcome measures, knee PROMs, knee scores, using knee PROMs, PROMs challenges, PROMs in practice orthopaedics, language barriers, cultural barriers, knee osteoarthritis, knee pathology, diagnosing knee pathology, visual PROMs, video, using visual media in healthcare, quality control of questionnaires.

Inclusion criteria was based on relevance to PROMs and their implementation in orthopaedics. Articles were included if they referred to PROMs of the knee but were not limited to the knee only. Articles were excluded if they were in a language other than English.

Background

Measurements are an integral part of evidence-based medicine and provide the necessary information for clinicians to make decisions in patient management.[1] Clinicians make use of measurements in practice to determine a patient's health status, diagnose a condition, prescribe what needs to be done in terms of treatment and quantify the success of an intervention. There is an ongoing discussion of whether to use subjective or objective methods, or even both, however the latter is recommended to assess a patient's level of activity limitation.[2]

Over the last two decades there has been an increasing interest in developing and using patient-reported outcome measures in clinical practice.[1] A patient-reported outcome measure, also known as a PROM, is commonly used by healthcare providers as a means of assessing health-related quality of life (HRQoL) and function at any given time.[3] Some PROMs were originally designed for research purposes and to determine the success of the treatment.[4] Treatment success would be tested by requesting that the patient complete the questionnaire before intervention and then again sometime after the intervention to detect any changes in condition. Surgeons also use it in conjunction with a physical evaluation or objective assessment as an aid to clinical decision making, predominantly in osteoarthritis (OA) patients in the case of this thesis.[5]

A PROM is understood as a measure of subjective health, which is an established criterion for the evaluation of therapeutic measures.[6] This relies on the patients views of their own health status that can leave room for bias. PROMs often take the form of both disease-specific eg. Knee Osteoarthritis Outcome Score and general health measures eg. SF-12.[7,8] A disease-specific PROM focuses on one condition or aspect of healthcare whereas general health measures aim to provide the clinician with an overall health status. Both are important in establishing a level of HRQoL.

Impact of knee injury on Health-Related Quality of Life

A history of knee injury is often associated with long-term complications, including decreased function and HRQoL, increased pain and higher risk for the development of knee Osteoarthritis (OA).[9,10] OA is the most prevalent chronic joint disease in the world, and is associated with significant deteriorations in HRQoL and can be extremely painful.[11,12] Research indicates OA is good example of where PROMs are used successfully in clinical practice. The two most affected joints are the hip and knee, which are arguably the most important joints in performing Activities of Daily Living (ADLs).[13] According to the Global Burden of Disease (GBD) 2010 study, hip and knee OA was ranked the 11th leading cause of disability due to dramatically decreasing one's ability to perform ADLs.[14] Therefore, management of such a condition would require a comprehensive assessment tool that analyses physical function and limitations.[15]

Commonly used Knee-Specific PROMs

Knee-specific PROMs are classified as disease-specific and are known for their use in the orthopaedic sector of medicine.[16] Research demonstrates that a patient's perspective of the knee can provide information that a clinician's assessment may not. For example, without input from the patient, a clinician may not accurately quantify the level of pain a patient experiences in the knee when walking, because they cannot feel how the patient subjectively experiences the pain themselves. This degree of pain can change a diagnostic outcome and therefore a subjective point of view can influence the end result and in turn, the treatment plan.

The below mentioned PROMs are commonly used for the knee assessment in orthopaedics. They have also been translated into various languages with the intention of increasing its use in healthcare in foreign countries.

Oxford Knee Score (OKS)

The OKS is a 12-item questionnaire designed to determine the outcome of a total knee athroplasty (TKA) based on the patient's perception. The OKS is not divided into sub-sections, however it does require the patient to report on levels of pain, stability and functional limitations. Unlike the KOOS and WOMAC, which are used in various cases, the OKS was only intended on for use with knee surgery.[17] This as well as its low patient burden are seen as an advantage. The score is known for its high response rate and sensitivity to clinical change, which is important when determining the outcome of TKR.

Despite the OKS being one of the most widely used knee PROMS, several issues have been raised. The score was originally rated on a scale of 1-5, where 1 is considered "excellent" or no problems and 5 being the worst or "poor". This was the only score that was inversely proportional to the KOOS-PS ie. a higher score represents a poor result. There has been much confusion with the method of scoring. Murray et al. suggests that the score can be converted to a different scale eg. 0 – 4 instead of 1 – 5.[18,19] It can also be inverted so that 1 is considered poor and 5 is considered excellent. In the present study, when comparing the PROMS, the OKS was inverted so that the higher score represents a positive result and a lower score represents a negative result.

Another issue was found regarding the wording of questions and responses. These have often been misinterpreted by patients. Question 4 asks the patient how long a patient can walk for before pain becomes severe. The extreme response option is "not at all". This is often mistaken as it being no problem and no pain is experienced.[18]

The OKS has been translated to a larger number of different languages including Chinese, German, Japanese, Swedish and Thai.[20]

Western Ontario & McMaster Universities Osteoarthritis Index (WOMAC)

The WOMAC was the first patient-based outcome score developed for OA.[21] It is a 17-item questionnaire with 3 sub-sections, namely pain, stiffness and function. The score has been validated for the use of knee and hip OA in various languages and is used frequently used around the world.[22,23] The WOMAC exists in the Likert format, the Numerical Rating (NRS) and the Visual Analogue (VAS) Format.[24] It originally had more subscales such as emotion and social dimensions but were left out in further validations according to the Outcome Measures in Rheumatology (OMERACT).[25] The WOMAC used in the present study had 3 subscales namely: pain, stiffness and function. Limitations of culturally adapting the WOMAC include daily functions such as stair climbing, transportation, bathing or toilet habits where it can vary from country to country.[26] Word usage is another challenge in the cultural adaptation of the WOMAC. Interpretation of words around the world can differ considerably. For example, the word "extreme" may not be appropriate in some parts of the world and the term "very severe" may be more so.[27] The use of the word "nocturnal" was discovered to be a commonly misinterpreted word in the present study, and the term "night pain" may have been better suited for the current population. The WOMAC is available in the 3 most commonly spoken languages: 1) Chinese; 2) Spanish; 3) English.[21,28,29]

The Knee Osteoarthritis Outcome Score (KOOS) and its Physical Function Shortform (KOOS-PS)

The KOOS is a knee-specific instrument, developed to assess the patients' opinion of their knee condition.[30] The original KOOS has 42 items that is divided into 5 sub-sections, and uses English as medium of instruction. This, however, can become impractical and challenging to administer, especially in 3rd world countries where

education levels are lower and time constraints exist. The KOOS-PS however is a 7-item questionnaire only addressing physical function. These 7 items are based on functions needed to perform ADL's. Each question is answered on a scale of 0 to 4, with 0 being "no difficulty" and 4 being "extremely difficult." Research suggests that the KOOS-PS has been converted into 4 different languages. These include Turkish, French, Swedish and Portuguese.[20,31-33]

One of the limitations of the KOOS is that patients can choose to answer the rate of difficulty based on whether it applied to them or not. For example, squatting was a movement they many not have done, and therefore will choose no difficulty instead of trying to do it and feel.[34] This is a misinterpretation that can impact the result tremendously. The original KOOS-PS validation showed promising results for the physical functioning measure, but it did not have enough for responsiveness.[35]

The KOOS was chosen for conversion because it is already being used in the relevant settings which include physiotherapy and orthopaedic surgery. The KOOS is also validated for the use of knee conditions other than osteoarthritis.[36] The KOOS-PS was specifically chosen because it has only the functional component, which can be easily illustrated and needs less time to administer than the full KOOS. This is essential in the public sector where there is a high patient load and time constraints.

Implementation of PROMs

As patient-centred care has become the standard of modern health care, PROMs are becoming more important in informing the allocation of health-care resources and the provision of guidelines for optimum care and management.[37] Patient's views can be summarised using PROMs, and these summaries can inform their health care providers.[38]

In addition to the importance of a patient's perception, PROMs are also conveniently administered. PROMs may take the form of traditional pen-and-paper questionnaires or various electronic counterparts including touch screens, tablets or mobile phones.[39] Exploring visual media, Walker et al. believes that images have the ability to cross the cultural barrier.[40] This is in support of Terwee's computer-administered Animated Activity Questionnaire (AAQ) which was developed to measure physical functioning in patients with hip or knee OA.[41] This allows clinicians to receive important information from their patients regarding their patient's functional status, without running risk of influencing the patients' perceptions of their care or outcome. If the questions were asked by the clinician, it may be asked in such a way that the patient may change their perception and this could influence the outcome.

Regardless of the form the PROMs take, there are challenges faced when implementing these PROMs. These may include obstructions in the implementation of a PROM or preventing accurate measurements or outcomes of the questionnaire. Obstructions include language or cultural barriers, time and acceptability to healthcare and technology.[42-45] An example of preventing accurate measurements may be dishonesty with

intention of avoiding worst case interventions, or a patient may have a lack of understanding or low comprehension of the questionnaire. This research hypothesized that challenges faced when administering these PROMS are largely related to the cultural or language barrier.

Language and Cultural Barriers

For the purpose of this study, a barrier was defined as a circumstance that prevents communication or progress.[46] These circumstances are largely related to either language, literacy or cultural barriers, particularly when a PROM validated in the English language is implemented in countries with high levels of poverty and low levels of education.[42-45] With increased demand for use of PROMs throughout the world, understanding the impact that language and cultural barriers, across different contexts have on these measurements, is critical. PROMs require the ability to read and understand the questions being asked in a written format[47], but unfortunately not everyone has this ability in our clinical setting.

According to the United Nations Educational, Scientific, and Cultural Organisation (UNESCO), almost 25% of adults in the world are still considered illiterate.[48] Gogtay et al. used a validated WOMAC on patients in India, where about one-third of the world's illiterate population lives and found that several questions were not understood by the patients.[42,49] It was observed that the majority of the PROMs used in orthopaedics on this population group were written at such a high linguistic level that the likelihood of most recruited patients being able to read or comprehend them were minimal.[47] Seminal literature suggested that PROMs should be written at or below the average literacy level,[47] which is clearly not the case for PROMs designed in England and used in South Africa.

Factors influencing completion rates for PROMs were previously assessed in total joint arthroplasty patients. In 2013 a study by Schamber et.al, acceptance, referring to completion rates, of the questionnaire was lower among patients who were over 75, Hispanic or Black, had medical aid, in total knee arthroplasty patients and revision total joint arthroplasty patients.[45] They argue that these findings demonstrate that responsiveness differs between cultural and age groups. The study suggested that the patient's willingness and confidence to complete the assessment was associated with a lower health literacy.[50] Health literacy is defined as the ability to perform basic reading and numerical tasks required to function in the healthcare environment.[51]

In most low to middle income countries, where several languages are spoken, or a significant proportion of the population is illiterate, clinicians need to provide considerable explanation without attempting to influence the response.[42] If the response is influenced, the score or outcome of the evaluation is compromised and in essence, no longer valid. This is one of the main challenges in using PROMs in our clinical practice in South Africa.

Quality Criteria for a Patient Reported Outcome Measure

PROMs that are accepted and used in clinical practice require validation. This thesis is a validation study and therefore certain standards need to be met before it may be used in clinical practice. This means proving that these instruments measure what they are supposed to measure. This can be assessed via psychometric properties of the assessment to ensure specific criteria are met. The majority of validation studies for clinically used questionnaires follow a similar protocol and assessment standards. The validation of the original KOOS used the properties reliability, validity and responsiveness (Fig. 1) according to Liang & Jette.[52] Since then, the method of validating PROMs has been refined.

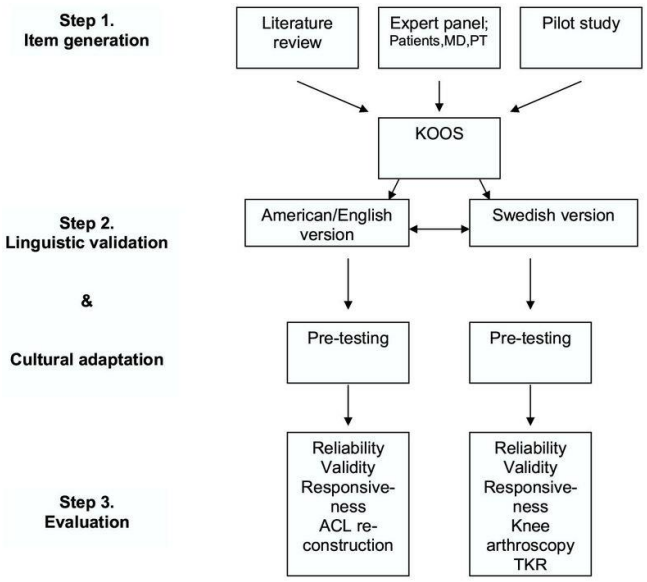

Figure 1. The original validation process of the KOOS.[8]

COSMIN (Consensus-based Standards for the selection of health status Measurement Instruments) is a method used to establish the above criteria.[53] Initially, Terwee et al. defined eight available quality criteria properties, namely: "1) Content Validity 2) Internal Consistency 3) Criterion Validity 4) Construct Validity 5) Reproducibility 6) Responsiveness 7) Floor and Ceiling effects 8) Interpretability."[54] At the time there were a few articles that offer quality criteria for the evaluation of health questionnaires. The most recognised were from the Scientific Advisory Committee (SAC) of the Medical Outcomes Trust.[55] With the quality criteria open for discussion and refinement, in 2010, a checklist was formulated from these developments to assist in the process of evaluating health related questionnaires.[53] This is known as The COSMIN checklist which contains 10 measurement properties (Table 1.)[53,54]

Table 1. The COSMIN Checklist: 10 Measurement properties.

CHECK	MEASURMENT PROPERTY
	Internal Consistency
	Reliability
	Measurement Error
	Content Validity
	Structural Validity
	Hypothesis Testing
	Cross-Cultural Validity
	Criterion Validity
	Responsiveness
	Interpretability

Research gap

PROMs do not always provide a true measure of culturally-sensitive function and often, physical function cannot be effectively illustrated in written format, especially for low-middle income countries. [44] Therefore, a PROM that can cross the cultural and language barrier would be extremely useful. A PROM which requires minimal literacy and language skills to complete may increase the responsiveness of the PROM and reduce the need to translate a commonly used written PROM into other languages. Specific to the KOOS score, one person may read, "Rise from sitting" and think using the arms are appropriate to lift themselves off the chair. Another may interpret the same instruction without using the arms. This can drastically affect the score by judging the level of difficulty. With a video demonstration, one can set a movement standard for functions to be evaluated subjectively without this barrier of written language. Guillemin et al. argues that, "clinicians and researchers without suitable outcome measures in their own language have two choices: (1) to develop new measures, or (2) to modify measures previously validated in another language, known as a cross-cultural adaptation process."[56] With a sufficiently validated video score, this may not be the case anymore. Therefore, the research gap is to develop a PROM in video format which minimizes the influence of the patient's reference frame when comprehending the questionnaire, without the need to read in the relative language, or determine the movement standard of the function in a questionnaire.

Research Aims, Questions and Hypotheses

Aim

This thesis aimed to produce a video version of the KOOS-PS and assess its validity, internal consistency and reproducibility to create a more diverse PROM that can be universally implemented.

Research Question

The main research question was: Can the developed video score assess patient-reported knee function with similar internal consistence and reproducibility to existing, written knee-specific PROMs, and thus, be effectively used in the South African healthcare system?

Research Hypothesis

The main hypothesis was that the converted video score would have similar outcomes to other knee-specific PROMs, be well accepted and culturally adaptable, and therefore be validated to measure the impact knee pathologies have on an individual's function in Cape Town, South Africa.

The next chapter will describe the methodology which was used to answer this research question and test our hypothesis.

CHAPTER 2: METHODS

This Chapter will describe the statistical analysis and methodology used in the conversion and validation of the video score. The study was divided into two stages. The KOOS-PS video conversion protocol is explained in the first section. The validation of the video score in a clinical cohort is then explained in the remaining sections. Section two will cover the patient recruitment process, statistical analysis, and psychometric properties used.

Converting the KOOS score into a video

The conversion procedure was carried out in two phases. First, the activities of daily living described in the KOOS-PS were converted into video illustrations. Seven videos, of a length no longer than 8 seconds each, were recorded. Each video demonstrated the respective representative action in the written version of the knee score questionnaire (example enclosed as a link). Each was recorded using a fixed camera and Kinovea 0.8.15 (France, 2006, Joan Charmant and Contributors) for editing. Simplicity and clarity of action was emphasised to minimise bias in the interpretation of the action. These ADLs were consistent with the KOOS-PS. They included: Rising from Bed; Putting on/Taking off Socks; Rise from Sitting; Bending to floor; Twisting/Pivoting on injured knee; kneeling; Squatting.

Second, to minimise cultural-bias, the videos were reviewed by a panel consisting of the principle and local investigators, as well as medical students in the Department of Orthopaedic Surgery, all of whom have a medical background and were registered with the Health Professions Council or South Africa (HPCSA). The videos were well understood and accepted with no necessary changes.

Once the videos had been approved, they were embedded into an online survey. Survey Monkey (1999, San Mateo, California, USA) was used to capture the data online and administer the questionnaire. A back-up version of the video score was created in Microsoft Powerpoint in order to avoid possible accessibility problems such as lack of internet connectivity. A Likert scale grading system was converted into icons that has five levels of difficulty. These levels ranged between 0 and 4, as was used in the written KOOS-PS. A verbal explanation to complete the video score was given. Patients were prompted to choose a face of the Likert Scale after watching the video relating to their current knee function. This prompt was not standardised. The image in figure 2 shows the grading system used. This scale was embedded beneath each video in order for the patient to rate the difficulty they experienced in performing the movement described.

Figure 2: The Likert scale represented by a set of smileys. The scale from Happy to Sad face (Left to Right) represent values of 0-4 respectively.

Figure 2. Likert scale in form of smileys.

Patient Recruitment

The video version of the score, along with two other questionnaires, the Oxford Knee Score and the Western Ontario & McMaster Universities Osteoarthritis Index, were then tested on 102 English-speaking patients suffering from knee pathology. The patients participating in the study were recruited at the knee clinic of the department of Orthopaedic Surgery, University of Cape Town, Wards D14 and J22 at Groote Schuur Hospital, private physiotherapy and biokinetics practices, as well as local sports clubs.

Before inclusion in the study, all patients received an information pack and were required to complete written informed consent. The questionnaires were completed by the patients without assistance or influence by others.

Patients were divided into groups based on their education levels. These were classified as follows:

- High education – patients who have completed tertiary education
- Intermediate education – patients who have completed secondary schooling (high school)
- Low education – patients who have not completed schooling

Inclusion and Exclusion Criteria

Patients were included if they:

- Had pain, an injury or non-traumatic pathology of the knee
- were older than 18 years of age

Patients were excluded if they:

- were unable to walk or in a wheelchair
- had any visual impairment/s that hampered the video interpretation
- could not read or write
- did not speak English
- incomplete score (more than 2 questions missing in the knee scores).

Reliability

Huber et al. defined reliability as a measure of consistency or degree of dependability.[57] There are two major components, internal consistency and reproducibility or test–retest reliability.[58]

Internal consistency can be defined as the PROM's items ability to measure the same concept.[59] Cronbach's coefficient alpha was used to assess internal consistency. It ranges between the values of 0 and 1. The higher the Cronbach's alpha, the higher the correlation between the questions, which provides a more specific evaluation of a defined parameter, in this case ADL's, by the questions.[57] A Cronbach's alpha of 0.65 is regarded as the lower acceptable limit of correlation. A value of 0.8 is a good correlation and is acceptable in clinical practice. Results ranging 0.8–0.95 are considered excellent values and indicate a strong correlation. A Cronbach's alpha above 0.95 indicates that there are questions that deal with the same parameter and therefore, should be regarded as redundant.[57]

The test–retest reliability, also known as reproducibility, is the ability of a PROM to yield the same results when completed on separate occasions, under the same conditions. Various studies use different time intervals between test and retest of PROMs. The time was often based on the pathology that the PROM was being validated for. Intervals between 1 and 2 weeks were often seen in chronic pathology such as osteoarthritis.[34] The shorter time intervals such as 1-6 days are often seen in acute pathology such as ACL tears or focal cartilage lesions.[60,61] In the present study, we included multiple knee pathologies, both chronic and acute. Marx et al. found no statistical difference between 2 days and 2 weeks when including multiple pathologies.[62] Therefore, retesting occurred within 72 hours ie. 3 days, via the online survey or a revisit to the hospital or on appointment bases. The Pearson correlation coefficient was used to determine the correlation between the total results of both tests, resulting in the measure of reproducibility. A Pearson correlation coefficient (r) ranges between 0 and 1, where 0 indicates no reproducibility and 1 indicates a perfect correlation.[57] The rating scale can be observed below in table 2.

Validity

Validity is the degree to which a PROM "measures what it is supposed to measure."[57] This study assessed the construct validity of the converted video score by comparing its results with that of other scores. Construct validity is based on the extent to which a certain score can relate to other scores that were administered at a single point in time.[63] The Pearson correlation coefficient was used to determine this between the converted, video version and two similar patient reported outcome score (i.e. OKS and WOMAC). The rating scale can be observed in Table 2.

Table 2. Rating scale of the Pearson r Correlation[64]

Rating	***r***
Poor	0.00-0.20
Fair	0.21-0.40
Moderate	0.41-0.60
Good	0.61-0.80
Excellent	0.81-1.00

A Bland and Altman (BA) Plot is a graph used for the interpretation of method-comparison studies.[65] The BA plot was used to measure the difference of the test pair, KOOS-PS written questionnaire and the converted video version, plotted against the means. The plots closer to zero indicate that people received the same or similar results with the video version as they did with the written score.

Comprehensibility and acceptance

All patients received the converted score prior to the other scores. The time needed to answer the questions of the video score was documented in 50 of the patients. Comprehensibility and acceptance of the questionnaire was evaluated based on how questions answered or left unanswered. Questions that were left unanswered were evaluated in accordance with the authors of the original WOMAC. For one or more missing items, the answers were imputed by calculating the average of the other items.[66]

Descriptive statistics of the patient demographics were produced. This included the number of patients, mean age, gender split, educational level and relevant knee pathology categories.

This study aimed to recruit approximately 100 patients and retest 50% of them. This was taken from the guidance of Terwee et al. where a positive rating is given to a sample size of at least 50 patients.[54] Other validation studies of the KOOS-PS used nothing less than 85 included patients.[67-70] The number initially recruited was 102 patients, however after excluding a number of patients, only 89 patients were included for statistical analysis.

Ethical Compliance

Protocol approval was obtained from the Human Research Ethics Committee. (Reference number HREC 139/2016). The protocol is attached in the addenda on page 52. The study was conducted in accordance with the Declaration of Helsinki [2013], International guidelines for Good Clinical Practice (ICH 1997), The

Department of Health: Ethics in Health Research: Principles Structures and Processes, 2004 and according to national guidelines of Good Clinical Practice [National Department of Health 2006].

CHAPTER 3: RESULTS

This chapter highlights the main findings based on the statistical analysis and methodology of the previous chapter. The key findings are stated in the first section and highlighted in the figures and tables of this chapter. The main findings to support the message of this thesis are that the video score received similar results to that of other written, validated knee-specific PROMs, thus indicating a good validity. It received an excellent reproducibility score and internal consistency indicating it is reliable for use in clinical practice in Cape Town, South Africa. It was well accepted by all included patients, with only 3 unanswered questions in total.

Patient Demographics

Figure 3 displays the recruitment process in terms of inclusion and exclusion criteria. A total of 102 patients where approached for recruitment, 57 Patients at Groote Schuur Hospital, 42 at private practices and 3 at local sports clubs. The public sector was defined as government funded institutions and the private sector was defined as privately owned and affiliated to private medical aids in South Africa.

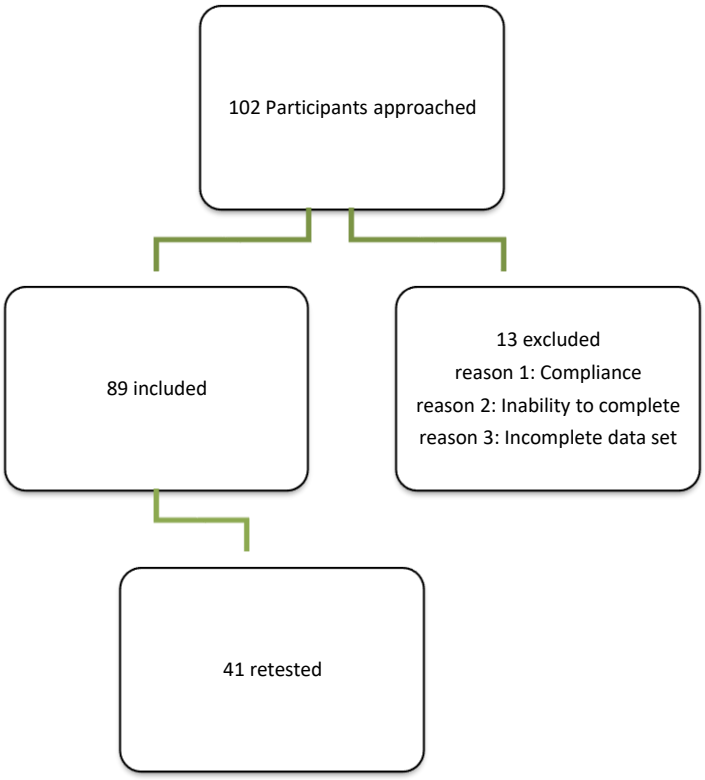

Figure 3. Patient inclusion diagram.

Eighty-nine of the one hundred and two recruited patients were included. The recruitment rate was 87.25%. A total of 13 (12.75%) were excluded from the study (Figure 3). Reasons for exclusion were questionnaires not handed back (N=7), poor vision or other complications making reading impossible (N=3), more than two omitted questions in any knee score (N=3).

Of the 89 patients that were included, 40 (45%) were male and 49 (55%) were female. The mean age of the population was 44.81 years. 47 (53%) were under the age of 45 and 42 (47%) were over the age of 45. A summary of their demographics and pathology is included in Table 3 below.

Table 3. Patient Descriptive Statistics.

PATIENTS (n)	89		
MEAN AGE (SD)	44.81		
GENDER (Male/Female)	40/49		
EDUCATION (All patients)	All patients	Public sector	Private sector
Higher	34	6	28
Intermediate	22	12	10
Lower	33	32	1
PATHOLOGY			
Osteoarthritis	31		
Ligament	21		
Meniscus	8		
Tendinopathy	8		
Trauma	4		
Non-specific anterior knee pain	12		
Other	5		

In terms of education level, the groups were similar in number. However, a majority of the patients that were recruited from the public sector had a lower educational level and a majority of the patients recruited from the private had a higher educational level.

Figure 4 categorises the patients according to their pathology. It is evident that the majority of the patients suffered from OA, followed by ligament damage.

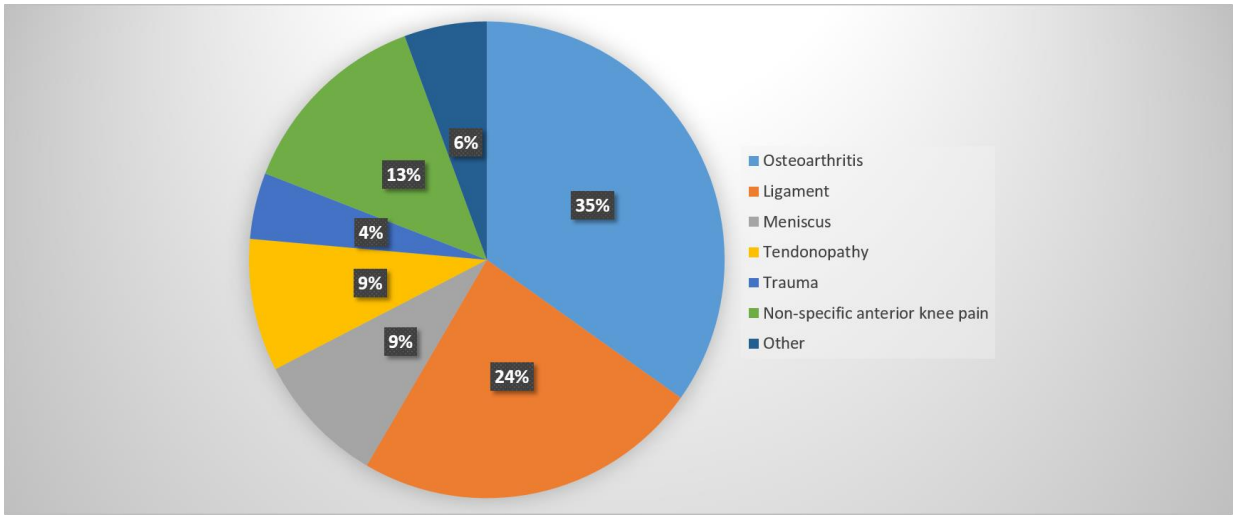

Figure 4. Patient Pathology Groups.

Reliability

Internal consistency (Cronbach's Alpha = 0.89) and reproducibility (Pearson r=0.91) was excellent. The mean difference between the initial test and retest was 0.07 (SD +/-3). This did not show a significant difference. The mean scores and standard deviation for each question of the baseline and retest, as well Pearson's Coefficients can be seen in Table 4.

Table 4. Reliability of the Video Score.

QUESTION	BASELINE SCORE (SD)	RETEST SCORE (SD)	PEARSON'S COEFFICIENT
1	0,78 (1,11)	0,76 (1,28)	0.61
2	0,81 (1,17)	0,93 (1,29)	0.84
3	1,12 (1,19)	1,20 (1,40)	0.90
4	1,27 (1,12)	1,22 (1,19)	0.74
5	0,90 (0,94)	0,98 (1,21)	0.72
6	2,68 (1,15)	2,59 (1,12)	0.81
7	2,05 (1,24)	1,88 (1,29)	0.74
Total	9,61 (5,98)	9,54 (7,16)	0.92

Validity

A Pearson Correlation coefficient was calculated for the video version of the KOOS-PS versus the Oxford Knee Score, WOMAC and the written version of the KOOS-PS. The correlations are presented in Table 5.

Table 5. Correlation between the Video Score and the OKS, WOMAC, and KOOS-PS.

KNEE PROMS	PEARSON'S CORRELATION
OKS	0.73
WOMAC	0.80
KOOS-PS	0.77

The BA plot in Figure 5 displays the comparison of the written KOOS-PS and the video score. The mean line was close to the zero, indicating that there was very little difference between the original written version of the KOOS-PS and the converted video score. Also, all but two points are within 2 Standard Deviations of the mean score, which indicates acceptable range. There were 3 outliers which may indicate a lack of comprehension of the scores.

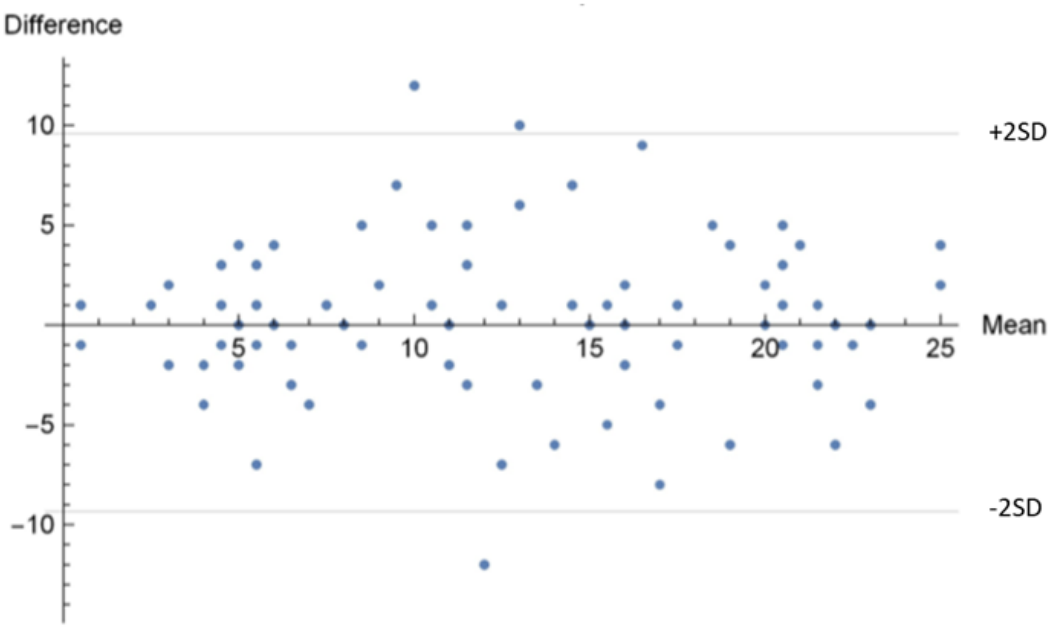

Figure 5. Bland and Altman Plot for the Video score vs Written KOOS-PS. SD=Standard Deviation.

Comprehensibility, Acceptance and Time

Time taken to complete the questionnaires was recorded for 43 patients, with a mean time to complete the video score of 79 seconds (SD +/-34). The comparison of the time taken between the video score and other written scores can be seen in Table 6.

Table 6. Mean Time (seconds) of 43 Patients to Complete Questionnaires.

VIDEO SCORE (SD)	OKS (SD)	WOMAC (SD)	KOOS-PS (SD)
79 (+/-34)	154 (+/-55)	150 (+/-64)	72 (+/-28)

All the questions were answered in the Video version and written score indicating a good acceptance and responsiveness. The WOMAC however had a total of 3 patients who had unanswered items. Patient 21 left out one item (Question 1 of the Stiffness Subscale), Patient 49 left out two items (question 2 of the stiffness subscale and question 2 of the physical function) and patient 56 left out one item (question 3 of the physical function subscale). The missing items were imputed by calculating an average of the rest of the items as described in the methods.

Floor and Ceiling Effects

According to Terwee et al.[71], floor and ceiling effects are said to be present if more than 15% of the respondents achieved the lowest or highest possible score. In the video score, the lowest possible score was 0 and the highest possible score was 28. In the present study, 1 of the 89 respondents achieved the highest score. In total, 1.12% (ie. 1/89) of the respondents achieved these extremes which suggests there are no floor or ceiling effects in the video score data.

CHAPTER 4: DISCUSSION

This chapter will interpret the findings and discuss them with regard to current literature. It will also highlight limitations of the study. This study aimed to create and validate a universal, knee-specific outcome score using video clips for demonstration and images for scoring. The KOOS formed the foundation for this as it is validated to assess a variety of knee conditions.

The established video score of this study proved to measure what it was made to measure with validity in patients with knee pathology. It measured a single concept without redundancy and the results were reproducible which make it a reliable measure. Acceptance was good and was culturally adaptable for patients of different economic levels. As hypothesised, the video score is valid, reliable and acceptable for use in knee pathology of patients in South Africa.

Patient demographics and characteristics

This study used patients from both the public and private sectors of healthcare. Other countries may have a different way of classifying but no other seminal validation study explore this demographic of patients, which plays an important role in the development of a patient-reported outcome score. In South Africa, a majority of the country's population is serviced by only 30% of qualified South African doctors, the remaining doctors all work in the private sector that services a lower portion of the country.[72] With a high patient load on clinicians, it is key to create comprehendible PROMs to avoid clinician-guided measures.

In this study, 50 of the included patients were from the public sector, and the remaining 39 were recruited from the private sector. The data indicates that more than half of the patients recruited in the public sector did not complete schooling and more than half of the patients recruited from private institutions completed tertiary education. This is in keeping with aforementioned statistics.

Various patient knee-pathologies were included which make it relevant for the variety of pathologies seen in the local practice of knee pathology. These included, osteoarthritis, meniscus damage, ligament damage, trauma, and overuse injuries. OA has proven to be the most prevalent knee condition.[11] Because the KOOS is already validated for multiple conditions, this research did not use a specific condition for the validation of the video version.[67,73,74]

Validity and reliability

As hypothesized, the converted video score correlated highly with other validated scores (Table 5). This indicates that the video score measures what it was made to measure. The video score correlated better with the WOMAC, followed by the KOOS-PS. This is in keeping with a study comparing the validity and responsiveness of the HOOS-PS and KOOS-PS with the WOMAC subscales.[75] In the study, a similar correlation was achieved between the KOOS-PS and the WOMAC as was achieved in the present study.

The video score displayed an excellent internal consistency score (Cronbach's Alpha 0.89). This means the score is consistent with the parameters. This result is almost identical to that of the written KOOS-PS, receiving a Cronbach's Alpha of 0.89 as seen in other studies comparing psychometric properties of different knee-specific PROMs.[75-77] The KOOS-PS has been translated into other languages. The converted video score displays a very similar internal consistency to those of the translated scores. The Arabic translation received a Cronbach's Alpha of 0.848, the Turkish translation a 0.904, and the Portuguese a 0.89.[68-70]

The Pearson correlation coefficient showed a good test-retest reliability. This indicates that the test is easily understood, reproducible and reliable to use. Because participants were required to do their retest within 72 hours of the baseline test, it minimized the likelihood of sensitivity to change. Many other validation studies allow more time between the baseline test and the retest. The original development of the KOOS used a 9-day time interval, in which the patients completed the test twice.[8] The French validation study of the KOOS used a 2-week interval.[67] We used 72 hours between tests to avoid any changes in the condition from the baseline to the retest.

Acceptance

The time taken for 43 patients showed good acceptance. The mean times to complete the OKS and the WOMAC were almost double that of the video score. In clinical practice, this could be a key factor for time saving in clinics with high patient numbers and few clinicians. All patients answered the questions and appeared to have understood what was required of them. Only 3 patients had unanswered questions and these were in the WOMAC questionnaire. All of the video score questions were answered which indicated a good acceptance.

Limitations

The present study has several limitations. The patients recruited were all from various socioeconomic backgrounds and were classified accordingly. The demographics may impact the outcomes due to their educational level. There were 34, 22 and 33 patients in the higher, middle and lower education groups respectively. This was not enough to achieve a significant difference between the groups and therefore, a subgroup analysis was not performed.

The initial development of the video score did not undergo a pilot study prior to testing on a cohort. During the data collection phase, some patients from the public sector had not been exposed to a digital device such as a laptop or tablet. This may impact the outcomes of the video score which was done on a laptop. A back-up version of the video score, made in Microsoft Powerpoint, was used in places where there were technical issues such as electricity or internet connection. This could have influenced the acceptance of the score as patients may have different technical skills. Another limitation is that we have not tested sensitivity to change (responsiveness) of the current study and this is still to be further investigated. The investigation into responsiveness to clinical change is an important factor in the validation of a PROM but this would require a

larger study. The present study is yet to be tested on actual illiterate individuals or individuals of other languages and cultures.

CHAPTER 5: CONCLUSION

This is the first validation study that converts a validated, written orthopaedic Patient Reported Outcome Score (PROM) into a video format. The study show that the video score is a reliable tool to use in clinical practice and achieved good acceptance across various educational and socio-demographic levels.

Future research is encouraged to investigate the effectiveness of the video score in different languages and settings. Also, PROMs should be developed to assess other joints and conditions. This will enable the video score to be used universally. Further investigation is needed to determine the impact of educational levels on the comprehension of the video score.

REFERENCES

1. Antunes B, Harding R, Higginson IJ, EUROIMPACT. Implementing patient-reported outcome measures in palliative care clinical practice: A systematic review of facilitators and barriers. *Palliat Med*. 2014;28(2):158-175.

2. Gandhi R, Tsvetkov D, Davey JR, Syed KA, Mahomed NN. Relationship between self-reported and performance-based tests in a hip and knee joint replacement population. *Clin Rheumatol*. 2009;28(3):253-257.

3. El-Daly I, Ibraheim H, Rajakulendran K, Culpan P, Bates P. Are patient-reported outcome measures in orthopaedics easily read by patients? *Clinical Orthopaedics and Related Research®*. 2016;474(1):246-255.

4. Dawson J, Doll H, Fitzpatrick R, Jenkinson C, Carr AJ. The routine use of patient reported outcome measures in healthcare settings. *BMJ*. 2010;340:c186.

5. Harris KK, Dawson J, Jones LD, Beard DJ, Price AJ. Extending the use of PROMs in the NHS--using the oxford knee score in patients undergoing non-operative management for knee osteoarthritis: A validation study. *BMJ Open*. 2013;3(8):e003365-2013-003365.

6. Najman JM, Levine S. Evaluating the impact of medical care and technologies on the quality of life: A review and critique. *Social Science & Medicine.Part F: Medical and Social Ethics*. 1981;15(2-3):107-115.

7. Jenkinson C, Layte R, Jenkinson D, et al. A shorter form health survey: Can the SF-12 replicate results from the SF-36 in longitudinal studies? *Journal of Public Health*. 1997;19(2):179-186.

8. Roos EM, Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee injury and osteoarthritis outcome score (KOOS)—development of a self-administered outcome measure. *Journal of Orthopaedic & Sports Physical Therapy*. 1998;28(2):88-96.

9. Lam KC, Thomas SS, Valier ARS, McLeod TCV, Bay RC. Previous knee injury and health-related quality of life in collegiate athletes. *Journal of athletic training*. 2017;52(6):534-540.

10. Kiadaliri AA, Lamm CJ, de Verdier MG, et al. Association of knee pain and different definitions of knee osteoarthritis with health-related quality of life: A population-based cohort study in southern sweden. *Health and quality of life outcomes*. 2016;14(1):121.

11. Bijlsma JW, Berenbaum F, Lafeber FP. Osteoarthritis: An update with relevance for clinical practice. *The Lancet*. 2011;377(9783):2115-2126.

12. Farr Ii J, Miller LE, Block JE. Quality of life in patients with knee osteoarthritis: A commentary on nonsurgical and surgical treatments. *Open Orthop J*. 2013;7:619-623.

13. Pereira D, Peleteiro B, Araujo J, Branco J, Santos R, Ramos E. The effect of osteoarthritis definition on prevalence and incidence estimates: A systematic review. *Osteoarthritis and Cartilage*. 2011;19(11):1270-1285.

14. Cross M, Smith E, Hoy D, et al. The global burden of hip and knee osteoarthritis: Estimates from the global burden of disease 2010 study. *Ann Rheum Dis*. 2014;73(7):1323-1330.

15. Dobson F, Hinman RS, Hall M, Terwee C, Roos EM, Bennell K. Measurement properties of performance-based measures to assess physical function in hip and knee osteoarthritis: A systematic review. *Osteoarthritis and cartilage*. 2012;20(12):1548-1562.

16. Beswick AD, Wylde V, Gooberman-Hill R, Blom A, Dieppe P. What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients. *BMJ Open*. 2012;2(1):e000435-2011-000435. Print 2012.

17. Dawson J, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. *The Journal of bone and joint surgery.British volume*. 1998;80(1):63-69.

18. Murray D, Fitzpatrick R, Rogers K, et al. The use of the oxford hip and knee scores. *The Journal of bone and joint surgery.British volume*. 2007;89(8):1010-1014.

19. Williams D, Blakey C, Hadfield S, Murray D, Price A, Field R. Long-term trends in the oxford knee score following total knee replacement. *The bone & joint journal*. 2013;95(1):45-51.

20. Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM. Measures of knee function: International knee documentation committee (IKDC) subjective knee evaluation form, knee injury and osteoarthritis outcome S. *Arthritis care & research*. 2011;63(S11):S208-S228.

21. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: A health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol*. 1988;15(12):1833-1840.

22. Angst F, Ewert T, Lehmann S, Aeschlimann A, Stucki G. The factor subdimensions of the western ontario and McMaster universities osteoarthritis index (WOMAC) help to specify hip and knee osteoarthritis. a prospective evaluation and validation study. *J Rheumatol*. 2005;32(7):1324-1330.

23. Bellamy N. WOMAC: A 20-year experiential review of a patient-centered self-reported health status questionnaire. *J Rheumatol*. 2002;29(12):2473-2476.

24. Woolacott NF, Corbett MS, Rice SJ. The use and reporting of WOMAC in the assessment of the benefit of physical therapies for the pain of osteoarthritis of the knee: Findings from a systematic review of clinical trials. *Rheumatology*. 2012;51:1440-1446.

25. Bellamy N, Kirwan J, Boers M, et al. Recommendations for a core set of outcome measures for future phase III clinical trials in knee, hip, and hand osteoarthritis. consensus development at OMERACT III. *J Rheumatol*. 1997;24(4):799-802.

26. Bellamy N. The WOMAC knee and hip osteoarthritis indices: Development, validation, globalization and influence on the development of the AUSCAN hand OA indices. *Clin Exp Rheumatol*. 2005;23(5):S148.

27. Bellamy N. WOMAC: A 20-year experiential review of a patient-centered self-reported health status questionnaire. *J Rheumatol*. 2002;29(12):2473-2476.

28. Xie F, Li S, Goeree R, et al. Validation of chinese western ontario and McMaster universities osteoarthritis index (WOMAC) in patients scheduled for total knee replacement. *Quality of Life Research*. 2008;17(4):595.

29. Escobar A, Quintana J, Bilbao A, Azkarate J, Güenaga J. Validation of the spanish version of the WOMAC questionnaire for patients with hip or knee osteoarthritis. *Clin Rheumatol*. 2002;21(6):466-471.

30. Roos EM, Toksvig-Larsen S. Knee injury and osteoarthritis outcome score (KOOS)–validation and comparison to the WOMAC in total knee replacement. *Health and quality of life outcomes*. 2003;1(1):17.

31. Gul ED, Yilmaz O, Bodur H. Reliability and validity of the turkish version of the knee injury and osteoarthritis outcome score-physical function short-form (KOOS-PS). *Journal of back and musculoskeletal rehabilitation*. 2013;26(4):461-466.

32. Ornetti P, Perruccio A, Roos E, Lohmander L, Davis A, Maillefert J. Psychometric properties of the french translation of the reduced KOOS and HOOS (KOOS-PS and HOOS-PS). *Osteoarthritis and cartilage*. 2009;17(12):1604-1608.

33. Goncalves R, Cabri J, Pinheiro J, Ferreira P, Gil J. Reliability, validity and responsiveness of the portuguese version of the knee injury and osteoarthritis outcome Score–Physical function short-form (KOOS-PS). *Osteoarthritis and cartilage*. 2010;18(3):372-376.

34. Roos EM, Toksvig-Larsen S. Knee injury and osteoarthritis outcome score (KOOS)–validation and comparison to the WOMAC in total knee replacement. *Health and quality of life outcomes*. 2003;1(1):17.

35. Perruccio AV, Lohmander LS, Canizares M, et al. The development of a short measure of physical function for knee OA KOOS-physical function shortform (KOOS-PS)–an OARSI/OMERACT initiative. *Osteoarthritis and cartilage*. 2008;16(5):542-550.

36. Roos EM, Lohmander LS. The knee injury and osteoarthritis outcome score (KOOS): From joint injury to osteoarthritis. *Health and quality of life outcomes*. 2003;1(1):64.

37. Devlin NJ, Appleby J. Getting the most out of PROMS. *Putting health outcomes at the heart of NHS decision making.London: King's Fund*. 2010.

38. Gibbons E, Hewitson P, Morley D, Jenkinson C, Fitzpatrick R. The outcomes and experiences questionnaire: Development and validation. *Patient related outcome measures*. 2015;6:179.

39. Keurentjes J, Fiocco M, So-Osman C, et al. Hip and knee replacement patients prefer pen-and-paper questionnaires implications for future patient-reported outcome measure studies. *Bone and Joint Research*. 2013;2(11):238-244.

40. Walker D, Robinson S, Jagatsinh Y, Adebajo A, Helliwell P, Rahman A. A survey of the images used on the arthritis research UK (ARUK) osteomalacia mind-map in relation to cultural background. *Journal of visual communication in medicine*. 2011;34(2):58-62.

41. Terwee CB, Coopmans C, Peter WF, et al. Development and validation of the computer-administered animated activity questionnaire to measure physical functioning of patients with hip or knee osteoarthritis. *Phys Ther*. 2014;94(2):251-261.

42. Gogtay NJ, Thatte UM, Dasgupta B, Deshpande S. Use of the WOMAC questionnaire in mumbai and the challenges of translation and cross cultural adaptation. *Indian J Med Ethics*. 2013;10(1):33-35.

43. Patel J, Lee JH, Li Z, SooHoo NF, Bozic K, Huddleston JI. Predictors of low patient-reported outcomes response rates in the california joint replacement registry. *J Arthroplasty*. 2015;30(12):2071-2075.

44. Konan S, Hossain F, Patel S, Haddad F. Measuring function after hip and knee surgery. *The evidence to support performance-based functional outcome tasks.Bone Joint J*. 2014:1431-1435.

45. Schamber EM, Takemoto SK, Chenok KE, Bozic KJ. Barriers to completion of patient reported outcome measures. *J Arthroplasty*. 2013;28(9):1449-1453.

46. Business Dictionary. Barriers to communication. . Http://Www.businessdictionary.com/definition/barriers-to-communication.html. Updated 2016. Accessed July/14, 2016.

47. Brown TD. CORR insights®: Are patient-reported outcome measures in orthopaedics easily read by patients? *Clinical Orthopaedics and Related Research®*. 2016;474(1):256-257.

48. Kickbusch IS. Health literacy: Addressing the health and education divide. *Health Promot Internation*. 2001;16(3):289-297.

49. Deshpande A, Desrochers A, Ksoll C, Shonchoy AS. The impact of a computer-based adult literacy program on literacy and numeracy: Evidence from india. *World Dev*. 2017;96:451-473.

50. Von Wagner C, Semmler C, Good A, Wardle J. Health literacy and self-efficacy for participating in colorectal cancer screening: The role of information processing. *Patient Educ Couns*. 2009;75(3):352-357.

51. Chew LD, Bradley KA, Boyko EJ. Brief questions to identify patients with inadequate health literacy. *health*. 2004;11:12.

52. H Liang M, M Jette A. Measuring functional ability in chronic arthritis. a critical review. *Arthritis & Rheumatology*. 1981;24(1):80-86.

53. Mokkink LB, Terwee CB, Patrick DL, et al. The COSMIN checklist for assessing the methodological quality of studies on measurement properties of health status measurement instruments: An international delphi study. *Quality of life research*. 2010;19(4):539-549.

54. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol*. 2007;60(1):34-42.

55. Lohr KN. Assessing health status and quality-of-life instruments: Attributes and review criteria. *Quality of Life Research*. 2002;11(3):193-205.

56. Guillemin F, Bombardier C, Beaton D. Cross-cultural adaptation of health-related quality of life measures: Literature review and proposed guidelines. *J Clin Epidemiol*. 1993;46(12):1417-1432.

57. Huber W, Hofstaetter JG, Hanslik-Schnabel B, Posch M, Wurnig C. The german version of the oxford shoulder score—cross-cultural adaptation and validation. *Arch Orthop Trauma Surg*. 2004;124(8):531-536.

58. Portney L, Watkins M. Validity of measurements. *Foundations of clinical research: Applications to practice*. 2000;2.

59. Nunnally JC, Bernstein I. Validity. *Psychometric theory*. 1994:99-132.

60. Salavati M, Akhbari B, Mohammadi F, Mazaheri M, Khorrami M. Knee injury and osteoarthritis outcome score (KOOS); reliability and validity in competitive athletes after anterior cruciate ligament reconstruction. *Osteoarthritis and Cartilage*. 2011;19(4):406-410.

61. Bekkers J, de Windt TS, Raijmakers N, Dhert W, Saris D. Validation of the knee injury and osteoarthritis outcome score (KOOS) for the treatment of focal cartilage lesions. *Osteoarthritis and cartilage*. 2009;17(11):1434-1439.

62. Marx RG, Menezes A, Horovitz L, Jones EC, Warren RF. A comparison of two time intervals for test-retest reliability of health status instruments. *J Clin Epidemiol*. 2003;56(8):730-735.

63. Davidson M, Keating J. Patient-reported outcome measures (PROMs): How should I interpret reports of measurement properties? A practical guide for clinicians and researchers who are not biostatisticians. *Br J Sports Med*. 2014;48(9):792-796.

64. Feise RJ, Menke JM. Functional rating index: A new valid and reliable instrument to measure the magnitude of clinical change in spinal conditions. *Spine*. 2001;26(1):78-87.

65. Dewitte K, Fierens C, Stockl D, Thienpont LM. Application of the bland-altman plot for interpretation of method-comparison studies: A critical investigation of its practice. *Clin Chem*. 2002;48(5):799-801; author reply 801-2.

66. Baron G, Tubach F, Ravaud P, Logeart I, Dougados M. Validation of a short form of the western ontario and McMaster universities osteoarthritis index function subscale in hip and knee osteoarthritis. *Arthritis Care & Research*. 2007;57(4):633-638.

67. Ornetti P, Perruccio A, Roos E, Lohmander L, Davis A, Maillefert J. Psychometric properties of the french translation of the reduced KOOS and HOOS (KOOS-PS and HOOS-PS). *Osteoarthritis and cartilage*. 2009;17(12):1604-1608.

68. Gul ED, Yilmaz O, Bodur H. Reliability and validity of the turkish version of the knee injury and osteoarthritis outcome score-physical function short-form (KOOS-PS). *Journal of back and musculoskeletal rehabilitation*. 2013;26(4):461-466.

69. Torad AA, El Kader HA, Saleh S, Torad M. Validity and reliability of the arabic version of koos-physical function short form in knee osteoarthritic patients. 2015.

70. Goncalves R, Cabri J, Pinheiro J, Ferreira P, Gil J. Reliability, validity and responsiveness of the portuguese version of the knee injury and osteoarthritis outcome Score–Physical function short-form (KOOS-PS). *Osteoarthritis and cartilage*. 2010;18(3):372-376.

71. Terwee CB, Bot SD, de Boer MR, et al. Quality criteria were proposed for measurement properties of health status questionnaires. *J Clin Epidemiol*. 2007;60(1):34-42.

72. Mayosi BM, Benatar SR. Health and health care in south Africa—20 years after mandela. *N Engl J Med*. 2014;371(14):1344-1353.

73. De Groot IB, Favejee MM, Reijman M, Verhaar JA, Terwee CB. The dutch version of the knee injury and osteoarthritis outcome score: A validation study. *Health and quality of life outcomes*. 2008;6(1):16.

74. Ebrahimi N, Jalaie S, Salsabili N, Ansari NN, Naghdi S. Knee injury and osteoarthritis outcome score in patients with isolated meniscus injury; validity and reliability. *Journal of research in medical sciences: the official journal of Isfahan University of Medical Sciences*. 2017;22.

75. Davis AM, Perruccio AV, Canizares M, et al. Comparative, validity and responsiveness of the HOOS-PS and KOOS-PS to the WOMAC physical function subscale in total joint replacement for osteoarthritis. *Osteoarthritis and Cartilage*. 2009;17(7):843-847.

76. Collins NJ, Misra D, Felson DT, Crossley KM, Roos EM. Measures of knee function: International knee documentation committee (IKDC) subjective knee evaluation form, knee injury and osteoarthritis outcome score (KOOS), knee injury and osteoarthritis outcome score physical function short form (KOOS-PS), knee outcome survey activities of daily living scale (KOS-ADL), lysholm knee scoring scale, oxford knee score (OKS), western ontario and McMaster universities osteoarthritis index (WOMAC), activity rating scale (ARS), and tegner activity score (TAS). *Arthritis Care & Research*. 2011;63(S11):S208-S228.

77. Peer MA, Lane J. The knee injury and osteoarthritis outcome score (KOOS): A review of its psychometric properties in people undergoing total knee arthroplasty. *Journal of Orthopaedic & Sports Physical Therapy*. 2013;43(1):20-28.

APPENDICES

Questionnaires and Data Capture Instruments

Online Survey Link: https://www.surveymonkey.com/r/3KQDX3S

Powerpoint Alternative

The KOOS-PS

Knee Injury and Osteoarthritis Outcome Score (KOOS) – Physical Function Shortform (KOOS-PS) English version

KOOS-Physical Function Shortform (KOOS-PS)

Today's date:_____/_____/_____ Date of birth: _____/_____/_____

Name: _____

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how well you are able to perform different activities.
Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can so that you answer all the questions.

The following questions concern your level of function in performing usual daily activities and higher level activities. For each of the following activities, please indicate the degree of difficulty you have experienced in the **last week** due to your knee problem.

1. Rising from bed

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

2. Putting on socks/stockings

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

3. Rising from sitting

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

4. Bending to floor

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

5. Twisting/pivoting on your injured knee

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

6. Kneeling

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

7. Squatting

None	Mild	Moderate	Severe	Extreme
❑	❑	❑	❑	❑

Oxford Knee Score (OKS)

English version for the United Kingdom

Prior to completing the Questionnaire please complete the following:-

Today's Date:

D	D	M	M	Y	Y	Y	Y
				2	0		

On which side of your body is the affected joint, **for which you are receiving treatment.**

Left ☐

Right ☐

Both ☐

If you said 'both', please complete the first questionnaire thinking about the right side. A second questionnaire, for the left side, will follow.

PROBLEMS WITH YOUR KNEE

Tick (✓) one box for every question.

1. During the past 4 weeks...

How would you describe the pain you usually have from your knee?

None	Very mild	Mild	Moderate	Severe
☐	☐	☐	☐	☐

2. During the past 4 weeks...

Have you had any trouble with washing and drying yourself (all over) because of your knee?

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

3. During the past 4 weeks...

Have you had any trouble getting in and out of a car or using public transport because of your knee? (whichever you would tend to use)

No trouble at all	Very little trouble	Moderate trouble	Extreme difficulty	Impossible to do
☐	☐	☐	☐	☐

4. During the past 4 weeks...

For how long have you been able to walk before pain from your knee becomes **severe**? (with or without a stick)

No pain/More than 30 minutes	16 to 30 minutes	5 to 15 minutes	Around the house only	Not at all/pain severe when walking
☐	☐	☐	☐	☐

5. During the past 4 weeks...

After a meal (sat at a table), how painful has it been for you to stand up from a chair because of your knee?

Not at all painful	Slightly painful	Moderately painful	Very painful	Unbearable
☐	☐	☐	☐	☐

6. During the past 4 weeks...

Have you been limping when walking, because of your knee?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
☐	☐	☐	☐	☐

7. During the past 4 weeks...

Could you kneel down and get up again afterwards?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

8. During the past 4 weeks...

Have you been troubled by pain from your knee in bed at night?

No nights	Only 1 or 2 nights	Some nights	Most nights	Every night
☐	☐	☐	☐	☐

9. During the past 4 weeks...

How much has pain from your knee interfered with your usual work (including housework)?

Not at all	A little bit	Moderately	Greatly	Totally
☐	☐	☐	☐	☐

10. During the past 4 weeks...

Have you felt that your knee might suddenly 'give way' or let you down?

Rarely/ never	Sometimes, or just at first	Often, not just at first	Most of the time	All of the time
☐	☐	☐	☐	☐

11. During the past 4 weeks...

Could you do the household shopping on your own?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

12. During the past 4 weeks...

Could you walk down one flight of stairs?

Yes, easily	With little difficulty	With moderate difficulty	With extreme difficulty	No, impossible
☐	☐	☐	☐	☐

Finally, please check back that you have answered each question.

Thank you very much.

The Western Ontario and McMaster Universities Osteoarthritis Index
(WOMAC)

Name:_____ Date:_____

Instructions: Please rate the activities in each category according to the following scale of difficulty: 0 = None, 1 = Slight, 2 = Moderate, 3 = Very, 4 = Extremely

Circle one number for each activity

Pain	1. Walking	0	1	2	3	4
	2. Stair Climbing	0	1	2	3	4
	3. Nocturnal	0	1	2	3	4
	4. Rest	0	1	2	3	4
	5. Weight bearing	0	1	2	3	4
Stiffness	1. Morning stiffness	0	1	2	3	4
	2. Stiffness occurring later in the day	0	1	2	3	4
Physical Function	1. Descending stairs	0	1	2	3	4
	2. Ascending stairs	0	1	2	3	4
	3. Rising from sitting	0	1	2	3	4
	4. Standing	0	1	2	3	4
	5. Bending to floor	0	1	2	3	4
	6. Walking on flat surface	0	1	2	3	4
	7. Getting in / out of car	0	1	2	3	4
	8. Going shopping	0	1	2	3	4
	9. Putting on socks	0	1	2	3	4
	10. Lying in bed	0	1	2	3	4
	11. Taking off socks	0	1	2	3	4
	12. Rising from bed	0	1	2	3	4
	13. Getting in/out of bath	0	1	2	3	4
	14. Sitting	0	1	2	3	4
	15. Getting on/off toilet	0	1	2	3	4
	16. Heavy domestic duties	0	1	2	3	4
	17. Light domestic duties	0	1	2	3	4

Total Score: _____ / 96 = _____%

Comments / Interpretation (to be completed by therapist only):

Consent Forms and Patient Information

INFORMATION FOR STUDY:

PATIENT REPORTED OUTCOME SCORES IN ORTHOPAEDICS – CONVERTED INTO VIDEO FORMAT

Institution	Individuals
Groote Schuur Hospital	DR. HELD, MR. DE ROOS, DR. KRUGER

THE INFORMATION BELOW WILL BE SUPPLIED TO ALL PARTICIPANTS TAKING PART IN THIS STUDY.

What is this study about?
We are carrying out medical research to find better ways of assessing the outcome of orthopaedic illnesses and injuries. We want to ask you questions to find out how you cope in your daily life. We would like to use this data to come up with an assessment tool, which will help us compare patients with each other and direct our treatment in a more structured and scientific way. We wish to convert a validated knee outcome score into a video format, to make future assessment of the score easier for people who cannot read or write.
You will be asked to complete the converted score first. The score is made up of 7 videos, each demonstrating a different movement. Below each video there is a set of 5 faces representing the degree of difficulty (sad face = difficult/incapable and happy face = no difficulty). After watching a video, please select 1 face that best describes the amount of difficulty you experience when performing the movement.
There are 4 more written scores that you will be asked to complete: KOOS-PS (7 items) – a joint specific questionnaire, Oxford Knee Score (12 items) - a joint specific questionnaire, WOMAC (17 items) - a joint specific questionnaire, SF-12 (12 items) – a general health survey.
We would also want to ask for your permission to phone you within 3 days to request that you complete the converted score again. This is to see if your answers match the score you have given us today.

What will it involve for me?
You will be treated no differently to anyone who does not take part in this study. It will involve a 15 min interview in which we will go over the questions with you.

Are there any risks or disadvantages for me taking part?
You will have exactly the same risks as someone with your condition not taking part in this study.

Are there any benefits for me?
There are no additional benefits for you and you will not be paid.

What happens if I refuse to participate?
All participation in research is voluntary. You are free to decide if you want to take part. If you do agree you can change your mind at any time and withdraw from the research. This will not affect your care now or in future.

Who will have access to information about me in this research?
All data will be registered to a study identification code. Only the local investigators have access to the key of the coding, so identifiable data will not leave the participating centres. Any additional staff involved (Research assistance, statisticians) with the research project will see your data WITHOUT your personal details.
The data will be stored for 10 years.

Who has allowed this research to take place?
Our departmental research committee and the local ethics committee have looked carefully at this work and agreed, that the research will be conducted properly and participants' safety and rights have been respected.

What if I have any questions?
You may ask any of our staff questions at any time. Your contact person for this study is:
Dr. M Held
Division of Orthopaedic Surgery, Knee Service
Secretaries: University of Cape Town, Mrs Priest, tel. 021 404 5108

If you want to ask someone independent anything about this research:
If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Chairperson of the Human Research Ethics Committee, Prof Blockman: 021 406 6492.

I understand the above information and agree to take part in this study

_____	_____	_____
(Initial and Name or sticker of participant)	(Date)	(Signature)

Protocol

Conversion of the Knee Osteoarthritis Outcome Score-Physical Shortform into a Video Format

Investigators:

Dr. M Held

Jordy de Roos

Dr. N Kruger

ROLES AND CONTACT DETAILS

Principal Investigator and site(s):
Dr. Michael Held
Division of Orthopaedic Surgery,
Groote Schuur Hospital
Email: email.held@gmail.com
Secretaries: University of Cape Town,
Mrs Priest, tel. 021 404 5108

Author and co-investigator:
Dr. Neil Kruger
Mr. Jordy de Roos

TABLE OF CONTENTS

1 BACKGROUND 4

2 OBJECTIVES AND HYPOTHESIS 4

3 STUDY DESIGN 4

4 METHODOLOGY 5

4.1 Conversion: 5

4.2 Patients: 5

4.3 Administration: 5

4.4 Questionnaires: 6

4.5 Statistical Analysis 6

4.6 Time needed, Comprehensibilty and Acceptance 7

4.7 Withdrawal of Patients from the Study 7

5 SCHEDULE AND TIME FRAME OF THE STUDY 7

6 DESCRIPTION OF RISKS AND BENEFITS 8

7 DATA REVIEW AND DATABASE MANAGEMENT 8

7.1 Data collection 8

7.2 Monitoring for quality 8

7.3 Database management 8

8 ETHICAL CONSIDERATIONS 8

8.1 Regulatory and ethical compliance 8

8.2 Informed consent 8

8.3 Participant compensation 8

8.4 Withdrawal 9

8.5 Insurance 9

8.6 Publication plan 9

9 REFERENCES 9

10 APPENDICES 63

ABBREVIATIONS AND DEFINITIONS

KOOS-PS - Knee Osteoarthritis Outcome Score – Physical Shortform

WOMAC – Western Ontario & McMaster Universities Osteoarthritis Index

OKS - Oxford Knee Score

SF-12 – Shortform 12

ADL – Activities of Daily Living

PROM – Patient-Reported Outcome Measure

GSH – Groote Schuur Hospital

OA - Osteoarthritis

PROTOCOL SYNOPSIS

Title	Conversion of the Knee Osteoarthritis Outcome Score-Physical Shortform into a Video Format
Sponsor	
Principal Investigator	Dr. Michael Held
Purpose and objectives	To test the reliability and validity of the converted video version of the KOOS-PS score
Study design	Cross-sectional study
Population size	Approximately 100 patients
Study duration	1 year
Statistical analysis	Internal consistency (reliability) will be tested using Cronbach's Coefficient Alpha. Pearson's Correlation will be used for both validity and test-retest reliability. Paired t-tests will also be used to compare score outcomes. The Bland and Altman Plot will be used to compare the video version of the KOOS-PS with the written KOOS-PS.

BACKGROUND

It is increasingly apparent that clinician-based assessments are often inaccurate and not reproducible (Drake et al., 1994 and Conboy et al., 1996). In addition, the concerns and priorities of the patient and surgeon may differ (Wright et al., 1994). Therefore, methods are required which elicit the patient's perception of the outcome (Amadio, 1993). This has led to increased interest in patient-based assessments (Olley and Carr, 2008).

There is a need for measures specifically designed for use in non-English-speaking countries, because cultural groups vary in disease expression and in their use of various health care systems (Huber et al., 2004). The KOOS-PS, a patient-based knee outcome score, has been translated to other languages, predominantly European languages. However, a translation of the KOOS-PS into an African language has not yet been found. Also, apart from the language barrier, approximately a third of South Africa is considered illiterate (Aitchison and Harley, 2006) and will not be able to complete a translated questionnaire accurately without a translator. Often health care workers only speak one or two of the languages spoken by their patients. This leads to challenges, as ad hoc and haphazard arrangements are made for interpreting by untrained personnel (Kilian et al, 2014). In Egypt, they have translated and validated an Arabic version of both the KOOS-PS (Torad et al., 2015) and the original KOOS (Almangoush et al., 2013). These are the only found, validated knee scores in a language relevant to the continent Africa. Attempts at a universal score using videos have been made, for example, the AAQ (Terwee et al., 2014). They produced 2 to 5 videos illustrating different levels of difficulty for 7 daily activities. They only used a sample size of 33 patients with hip and knee osteoarthritis and therefore further development and validation is needed. Another study attempted to validate the AAQ by comparing the AAQ to home-recorded videos of 11 basic activities and other written outcome scores (Peter et al., 2015). The sample size was only 22 patients and as a conclusion, further investigation with a larger sample size is needed.

Currently, there are no translated versions of the KOOS or any orthopaedic knee scores available in languages native to South Africa. Also, there are no validated PROMs based on pictures or videos to avoid language barriers. We aim to address this research gap by designing and validating a video based KOOS score.

OBJECTIVES AND HYPOTHESIS

Objectives

The objectives of the present study is to successfully convert the Knee Injury and Osteoarthritis Outcome Score-Physical Function Short Form (KOOS-PS) into a video format and to test its reliability and validity. In turn, creating an instrument or subjective test that is suitable for a broader range of patients.

Hypothesis

We predict that the converted video score will have the same outcomes as the other scores and therefore be validated to measure the impact knee pathologies have on an individual's function.

STUDY DESIGN

This will be an observational, cross-sectional study, in the form of questionnaires.

METHODOLOGY

Conversion

The KOOS-PS will be converted into a video format using a fixed GoPro hero 4 camera for recording and Kinovea for the editing. Videos of a length no longer than 10 seconds will be produced of the movements described in the written knee score questionnaire (example enclosed as a link). The videos will be reviewed by a panel consisting of the principle and local investigators as well as other students in the research group, all of whom have a medical background. Once the videos have been approved, they will be embedded into an online survey using Survey Monkey. The Likert scale grading system will be converted into icons that have an identical value, each graded into five levels of difficulty. This scale will be assigned to each video in order for the patient to rate how much difficulty they experience when performing that movement.

Patients

Inclusion criteria

- Patients with any knee pathology
- Ability to speak, read and write in English.

Exclusion criteria

- Patients with functional impairment precluding testing (ie visual impairment, stroke etc)
- Patients younger than 18 years of age
- Surgery to the afflicted knee within 2 months
- Illiterate patients unable to converse in, read or write in English

Recruitment and Demographics

- The patients participating in the study will predominantly be recruited at the department of Orthopaedic Surgery, University of Cape Town. Some may be recruited at private physiotherapy practices in Cape Town and sports clubs.

- All patients in the knee out-patient clinics and wards at GSH, physiotherapy practices and sports clubs with confirmed knee pathology will be considered eligible for inclusion.
- Approximately 100 patients will be participating in the study. They are assumed to be of a lower income level with lower levels of education than the average population and majority unemployed. This however has not been officially determined.

Administration

The video version of the score, along with 2 other questionnaires with similar patient reported assessments (ie. The OKS and the WOMAC), will be tested on recruited patients. The SF-12 will also be administered on all recruited patients. They will receive the converted score first, then the OKS followed by the WOMAC and SF-12. The KOOS-PS written version will be given as the last assessment for further investigation. Before participation proceeds, all patients will be given a detail briefing about the study procedures and will be required to complete written informed consent. The questionnaires will be completed by the patients without assistance or influence by others.

Questionnaires

Knee Osteoarthritis Outcome Score and it's Physical Shortform

The KOOS is a knee-specific instrument, developed to assess the patients' opinion about their knee problems of injury (Roos and Toksvig-Larsen, 2003). The original KOOS has 42 items split into 5 sub-sections. This however can become impractical and challenging to administer, especially in 3rd world countries where education levels are lower. The KOOS-PS however is a 7-item questionnaire only addressing physical function. These 7 items are based on functions needed to perform ADL's.

Oxford Knee Score

The OKS is a 12-item questionnaire designed to determine the outcome of a total knee athroplasty (TKA) based on the patients perception. The OKS is not split into sub-sections, however it does require the patient to report on levels of pain, stability and how they limit physical function.

Western Ontario & McMaster Universities Osteoarthritis Index

The WOMAC was the first patient-based outcome score developed for OA (Bellamy et al. 1988). It is a 17-item questionnaire with 3 sub-sections, namely pain, stiffness and function. The score has been validated for the use of knee and hip OA and frequently used around the world.

SF-12

The SF-12 is a 12-item generic health status measure. It is the summarised version of the SF-36 which has the same objectives but allows for a more efficient administration without the substantial loss of information (Ware et al., 1996). The SF-36 has been frequently used in validation studies such as translations of site-specific PROOM's. In this study we have

decided to use the SF-12 as there will more than one questionnaire to be administered at once.

Statistical Analysis

Reliability

Reliability is a measure of consistency or degree of dependability. It can be divided into two major classes: (1) internal consistency and (2) reproducibility or test–retest reliability (Portney & Watkins, 2000).

Internal consistency, which is a measure of equivalence, is the ability of a scale to measure a single coherent concept (Nunnally & Bernstein, 1994). Cronbach's coefficient alpha will be used to assess internal consistency. The range of a coefficient varies between 0 and 1. A higher Cronbach's coefficient alpha indicates a higher correlation between the questions, and therefore provides a more exact evaluation of a defined parameter, such as body function, by the questions. A Cronbach's alpha of 0.65 is regarded as the lower limit and a value 0.8 represents a good value. Results ranging 0.8–0.95 are regarded as excellent. A Cronbach's alpha above 0.95 should be regarded as an indication that there are questions that deal with the same parameter and therefore, should be regarded as unnecessary.

The test–retest reliability is the ability of a scale to yield the same results when administered on separate occasions, under the same conditions. This will be tested on the randomized sample of patients who would have repeated the questionnaire after 72 hours. The Pearson correlation coefficient will be used to determine the correlation between the total results of both tests, resulting in the measure of reproducibility. A correlation coefficient (r) of 0 indicates no reproducibility, whereas a value of 1 indicates a perfect correlation. The difference between the two tests will also be calculated. In order to detect systematic trends, confidence intervals for the mean difference will be calculated and paired t-tests will be performed. Confidence intervals close to a value of 0 will indicate no relevant systematic trends.

Validity

Validity is the degree to which a test measures what it is supposed to measure. In this case that means assessing the validity of the converted version. The Pearson correlation coefficient will be calculated between the converted, video version and two similar patient reported outcome score (i.e. OKS and WOMAC).

The Bland and Altman Plot will be used to compare the video version of the KOOS-PS to the written version. This will illustrate the correlation between each question.

Time needed, comprehensibility and acceptance

All patients will receive the converted score prior to the other scores. The time needed to answer the questions of the video score will be documented. Comprehensibility and acceptance of the questionnaire will be evaluated based on how many questions were answered and how many were left unanswered. The time needed for evaluation of the questionnaires will also be documented.

Withdrawal of patients from the study

A patient will be withdrawn from the study for the following reasons:

- If it no longer meet the inclusion criteria
- Failure to comply with the protocol
- At the discretion of the investigator (the reason will be recorded)

SCHEDULE AND TIME FRAME OF THE STUDY

Knee clinics: Wednesdays 07:00-13:00.

Setup and preparation will not exceed 1 hour per session. Time taken for each questionnaire will be documented. The data collection sessions will continue for the duration of the knee clinic which is approximately 6 hours. Each patient will be seen individually and about 5 minutes may be needed to move from one patient to the next. The sessions will be concluded within 6 months.

DESCRIPTION OF RISKS AND BENEFITS

This is an observational study and therefore imposes minimal-to-no risk on the patient.

DATA REVIEW AND DATABASE MANAGEMENT

Data collection

Results of the questionnaires and personal information ie. names, contact details, that are recorded will be kept securely by the principal investigator. All data captured will be captured on Excel and Word documents and stored on a password-protected computer by the principal investigator. Only the investigators will have access to this information.

Monitoring for quality

The Principal Investigator will provide direct access to source data/documents for monitoring, audits, ethics committee review, and regulatory inspection.

Database management

The confidentiality of records that can identify participants will be protected, respecting the privacy and confidentiality rules in accordance with regulatory requirements. All study-related documents will be stored for 10 years following study completion.

ETHICAL CONSIDERATIONS

Regulatory and ethical compliance

The relevant documents will be submitted to the Research Ethics Committee of the University of Cape Town. Approval of the protocol and any amendments will be obtained before implementation.

The study will be conducted in accordance with the Declaration of Helsinki [2013], International guidelines for Good Clinical Practice (ICH 1997), The Department of Health: Ethics in Health Research: Principles Structures and Processes, 2004 and according to national guidelines of Good Clinical Practice [National Department of Health 2006].

Deviations and exceptions from the protocol will be managed in accordance with the University of Cape Town's Research Ethics Committee procedures, which are in accordance with Good Clinical Practice guidelines.

Informed consent

Informed consent **(appendix)** will be obtained prior to receiving the converted score to complete. This will take place within the hospital clinic and therefore it is unlikely they will be able to discuss with family or friends before signing the consent form. The protocol and safety precautions will be explained before obtaining consent.

Participant compensation

There will be no compensation.

Withdrawal

Participants are free to withdraw from the study at any stage, without prejudice to them in any way.

Insurance

No insurance is required.

Publication plan

The study is aimed at the international orthopaedic community and the publication with the highest possible impact factor will be sought.

REFERENCES

Aitchison, J., & Harley, A. (2006). South African illiteracy statistics and the case of the magically growing number of literacy and ABET learners. Journal of education, 39, 89-112.

Almangoush, A., Herrington, L., Attia, I., Jones, R., Aldawoudy, A., Aziz, A. A., & Waley, A. (2013). Cross-cultural adaptation, reliability, internal consistency and validation of the Arabic version of the Knee injury and Osteoarthritis Outcome Score (KOOS) for Egyptian people with knee injuries. *Osteoarthritis and cartilage*, *21*(12), 1855-1864.

Amadio, P.C. (1993) Editorial. Outcomes measurement: more questions; same answers. J Bone Joint Surg Am, 75, 1583–4.

Bellamy, N., Buchanan, W. W., Goldsmith, C. H., Campbell, J., & Stitt, L. W. (1988). for Measuring Clinioallylmportant~ Patient_ Relevant. *trials*, *15*, 1833-1840.

Conboy, V.B., Morris, R.W., Kiss, J., Carr, A.J. (1996). An evaluation of the Constant-Murley shoulder assessment. J Bone Joint Surg Br, 78, 229–32.

Cronbach LJ (1951) Coefficient alpha and internal structure of tests. Psychometrika 16:297–334

Drake, B.G., Callaham, C.M., Dittus, R.S., Wright JG (1994). Global rating systems used in assessing knee arthroplasty outcomes. J Arthroplasty, 9, 409–17.

Huber, W., Hofstaetter, J. G., Hanslik-Schnabel, B., Posch, M., & Wurnig, C. (2004). The German version of the Oxford Shoulder Score—cross-cultural adaptation and validation. *Archives of orthopaedic and trauma surgery*,*124*(8), 531-536.

Kilian, S., Swartz, L., Dowling, T., Dlali, M., & Chiliza, B. (2014). The potential consequences of informal interpreting practices for assessment of patients in a South African psychiatric hospital. Social Science & Medicine,106, 159-167.

Nunnally JC, Bernstein ICH (1994) Psychometric theory. McGraw-Hill, New York

Olley, L. M., & Carr, A. J. (2008). The use of a patient-based questionnaire (the Oxford Shoulder Score) to assess outcome after rotator cuff repair. The Annals of The Royal College of Surgeons of England, 90(4), 326-331.

Perruccio AV, Lohmander, LS, Canizares M, Tennant A, Hawker GA, Conaghan PG, Roos EM, Jordan JM, Maillefert JF, Dougados M, Davis AM (2008) The Development of a Short Measure of Physical Function for Knee OA - KOOS-Physical Function Short-form (KOOS-PS) – An OARSI/OMERACT Initiative. Osteoarthritis and Cartilage 16: 542-550.

Peter, W. F., Loos, M., van den Hoek, J., & Terwee, C. B. (2015). Validation of the Animated Activity Questionnaire (AAQ) for patients with hip and knee osteoarthritis: comparison to home-recorded videos. *Rheumatology international*, 1-10.

Portney LG, Watkins MP (2000) Foundations of clinical research: applications to practice, 2nd edn. Prentice Hall, Upper Saddle River, NJ, USA

Roos, E. M., & Toksvig-Larsen, S. (2003). Knee injury and Osteoarthritis Outcome Score (KOOS)–validation and comparison to the WOMAC in total knee replacement. Health and quality of life outcomes, 1(1), 1.

Terwee, C. B., Coopmans, C., Peter, W. F., Roorda, L. D., Poolman, R. W., Scholtes, V. A., ... & de Vet, H. C. (2014). Development and Validation of the Computer-Administered Animated Activity Questionnaire to Measure Physical Functioning of Patients With Hip or Knee Osteoarthritis. *Physical therapy*, *94*(2), 251-261.

Torad, A. A., El Kader, H. A., Saleh, S., & Torad, M. (2015). VALIDITY AND RELIABILITY OF THE ARABIC VERSION OF KOOS-PHYSICAL FUNCTION SHORT FORM IN KNEE OSTEOARTHRITIC PATIENTS.

Ware Jr, J. E., Kosinski, M., & Keller, S. D. (1996). A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Medical care*, *34*(3), 220-233.

Wright, J.G., Rudicel, S., Feinstein, A.R.(1994). Ask patients what they want: evaluation of individual complaints before total hip replacement. J Bone Joint Surg Br, 76, 229–34.

APPENDICES

Questionnaires

- Converted Video Score Link: https://www.surveymonkey.com/create/survey/preview?sm=MAXbVeUiew8lb04upZkb52LXfpiOAOGilnjcCuBAHFU_3D

DRC and HREC Approval

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room ES3-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: sumayah.ariefdien@uct.ac.za
Website: www.health.uct.ac.za/fhs/research/humanethics/forms

15 March 2016

HREC REF: 139/2016

Dr M Held
Department of Orthopaedic Surgery
J-Floor
OMB

Dear Dr Held

PROJECT TITLE: CONVERSION OF THE KNEE OSTEOARTHRITIS OUTCOME SCORE PHYSICAL SHORT FORM INTO A VIDEO FORMAT (MSc-candidate-J de Roos)

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee (HREC) for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30 March 2017.

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

Please quote the HREC REF in all your correspondence.

We acknowledge that the following student, Jordy de Roos will also be involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938

2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI),and Declaration of Helsinki (2013) guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.