Patient-Reported Outcome Measures in the Repair of Chondral Defects: How Well Do the Scores Relate to Each Other?

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ABSTRACT

Introduction: In the repair of focal chondral defects, there are several patient-reported outcome measures (PROMs) that are used to assess the patient's well-being. However, the question remains as to how well one scoring system relates to another, which may restrict the comparison of results from different studies. Therefore, we examined the strength of correlations between the Lysholm and KOOS scores.

Materials and Methods: The data for this analysis was obtained from the Autologous Matrix-Induced Chondrogenesis (AMIC®; Geistlich Pharma AG, Wolhusen, Switzerland) knee registry, which is an ongoing, multicentre database designed to record changes over time in knee function and symptoms. This is done using the Lysholm score, the Visual Analogue Scale (VAS) for pain, and the five domains of the Knee injury and Osteoarthritis Outcome Score (KOOS). All patients had preoperative and postoperative scores at one-year follow up. The results were evaluated using the Spearman's rank correlation test.

Results: We identified 79 patients in the registry, all of whom were treated by the co-authors and had preoperative scores and postoperative scores at one year for the Lysholm, VAS, and the KOOS domains. The Lysholm score demonstrated a significant correlation ($p<0.0001$) to all KOOS domains. The correlation coefficients were 0.81, 0.82, 0.83, 0.84, and 0.76 for the KOOS domains of symptoms, pain, activities of daily living (ADL), quality of life (QoL), and Sport, respectively. The correlation between VAS pain and the KOOS domain for pain was significant ($p<0.0001$) but notably lower, with a correlation coefficient of 0.71.

Conclusion: Our data provides evidence that the outcome of the Lysholm knee score is strongly correlated with the KOOS scores, with the KOOS domains of ADL and pain exhibiting the highest correlation. Thus, it may be possible, through formulae calculations, to predict a KOOS score from the Lysholm score. With regard to assessment of outcomes over larger numbers of studies, the pooling of substantially more data could facilitate the conduct of systematic reviews and meta-analyses pertaining to the surgical treatment of chondral injuries of the knee.

INTRODUCTION

While the results of knee surgery are often discussed in terms of clinical examination or radiological findings, patients are likely to be more concerned with a reduction in symptoms and an improvement in function. In this regard, patient-reported outcome measures (PROMs) are a common means of assessing patients' pain and function following surgery.[1] While originally used to quantify the patient's perception of their symptoms and well-being, they are now also used in reimbursement[2] as well as regulatory decisions.[3] As the emphasis on patient-centred care continues to gain ground,[4] the use of PROMs, which by their very nature are subjective and based on the patient's experiences, will continue to play a noteworthy role in clinical practice.

Aside from PROMs, there are also outcome measures that are completed by the treating clinician (which could be the physician, nurse, or other allied health professional). Clinician-completed outcome measures typically have a clinical component to be assessed (i.e., radiological parameters or measurement of various physical signs) in addition to the patients' reported symptoms. Although these can provide a thorough and comprehensive assessment, the inclusion of clinical testing/observation as well as patient's subjective data can reduce the ease of implementation and compliance, especially when different investigators are gathering the data. Therefore, there is a risk of incomplete data collection. In contrast to clinician-completed tests, self-administered instruments involve the patients responding to questions by themselves. These had been previously considered to be unreliable, with a belief that such PROMs were too subjective.[5] However, this paradigm seems to have shifted over the years.[6] While it was once considered that clinician-completed instruments provided more objective data, the more recent focus on patient-centred care has noted that well-designed PROMs are good at determining health status. Furthermore, their value as outcome measures may be more appreciated among researchers.[7]

In terms of workload for the clinic, PROMs are less time consuming than functional tests, while still allowing to document the patients' perception of their outcomes.[8] In the knee, there are several PROMs currently in use, with varying levels of sensitivity, reliability, and effort.[9] Also, some instruments are specific to a procedure or joint structure.[10] However, in the published literature, the variety of instruments make it problematic to compare the results of a given study to another due to the aspects of physical function that a specific PROM is meant to quantify. While the Visual Analogue Scale (VAS) for pain is straightforward, and applicable to all joints, the variety of PROMs that have been used in the knee can make it difficult to compare outcomes in published studies.

To date, there have been few attempts to assess the relationship between PROMs and to determine how one score relates to another. It has been reported that functional tests do not correlate to PROM scores after cruciate reconstruction.[11,12] In contrast, a study that evaluated the relationships between various PROMs following meniscal repair noted that there were generally good correlations between the outcome measures.[13] However, the publication that reported good correlations did not include functional tests. Furthermore, the published data is limited to assessing outcome scores in the ACL and the meniscus. With regard to the repair of articular cartilage, and specifically focal chondral defects (FCD), there have been no publications that have evaluated the relationships between outcome scores even though there are a variety of PROMs that assess clinical outcomes. Therefore, in order to evaluate the relationship between two common outcome measures for the knee, we queried a registry of patients who have undergone single-stage surgery for chondral repair of the knee and assessed the data to determine the strength of the relationship between the outcome scores typically used to assess patient well-being following the surgical repair of focal chondral defects.

MATERIALS AND METHODS

Registry data

The data was based on a prospective registry for Autologous Matrix-Induced Chondrogenesis (AMIC®; Geistlich Pharma AG, Wolhusen, Switzerland) patients, which is an ongoing, multicentre database designed to longitudinally track changes in function and symptoms in patients who had undergone repair of chondral lesions via this procedure.[14,15] All patients whose data was analysed in this study have been seen for primary surgeries and then were seen postoperatively, at one year, as part of the standard of care. Outcomes in this registry were assessed using the Lysholm score, KOOS, and VAS for pain. Documentation is made on electronic case report forms, with surgeons having access to the registry via a web interface. Ethical approval for the registry was obtained from the ethics review board of the University of Lübeck (file No. 19-178).

Surgical treatment

All of the patients underwent single-stage surgery for full thickness chondral or osteochondral lesions in the knee (Outerbridge Classification III or IV). The index procedure, AMIC®, was performed using either a mini-open or arthroscopic approach, depending on surgeon preference. Following debridement and removal of degenerative or loose cartilage fragments, bone marrow stimulation (BMS) was performed using a 1.2mm drill or k-wire in order to perforate the subchondral bone plate. This was typically done to a depth of approximately 1cm, which resulted in the release of bone marrow stem cells into the defect. The prepared defect was then

covered with a collagen I/III membrane of porcine origin (Chondro-Gide®, Geistlich Pharma AG, Wolhusen, Switzerland) that had been matched, via the use of an aluminium template, to the defect size. Fixation of the membrane over the treatment site was done using either sutures or a fibrin sealant, depending on the surgeon's preference, as it has been shown that these two fixation methods provide equivalent results.[16] The knee was then held in an extended position for five minutes, and then the joint was flexed 10 times in order to verify the stability and position of the matrix. Finally, the incision was closed in layers and a drainage without suction was applied. The knee was immobilized for the first few days, after which continuous passive motion was started with restricted knee angles. This then progressed to limited weight bearing for approximately six weeks.

Postoperative rehabilitation

Although patients had been treated at different centres, the rehabilitation protocols adhered to the clinical standards following cartilage repair surgery.[17] These essentially follow progressive weightbearing over several weeks, along with recovery of range of motion and then restoration of strength before progression to functional exercises.[18]

Clinical outcome scores

Therapeutic outcomes were assessed on the basis of 3 PROMs: Lysholm, KOOS, and VAS. The Lysholm Scale, which produces a score from 0–100, has been in use for 40 years and is a validated measure of knee function[19] and has been used for 20 years in the assessment of outcomes for chondral injuries.[20] The KOOS differs from the Lysholm in that it is composed of five domains: symptoms, pain, sport and recreation, quality of life (QoL) and activities of daily living (ADL).[21] The KOOS was originally developed as an outcomes assessment in patients who are younger and physically active and provided an alternative to the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) score, which was commonly used for arthritis and degenerative cartilage injuries.[22] As an outcome measure, the KOOS is reliable, valid, and responsive.[23] While the KOOS and Lysholm are indexed scores that range from 0–100, the VAS scale is quite simple, and it ranges from 0, indicating no pain, up to 10, which indicates the worst pain the patient has ever known.

Table I
Physical characteristics of the patients

	Mean ± standard deviation
Age, years	36.2 ± 12.3
BMI	25.4 ± 3.7
Defect Size, cm^2	2.9 ± 1.2

Table II
The mean scores, pre- and postoperative

	Preoperative	Postoperative
Lysholm	48.5 ± 18.6	84.9 ± 12.0
VAS	5.2 ± 1.9	2.0 ± 1.5
KOOS		
Symptoms	53.2 ± 20.9	83.7 ± 14.7
QoL	28.8 ± 16.6	64.7 ± 23.4
Pain	55.2 ± 17.2	89.0 ± 9.6
ADL	57.9 ± 20.3	89.9 ± 7.5
Sport	24.1 ± 18.7	66.4 ± 23.5

Table III
The correlation matrix for the PROM scores that had been entered into the registry. All p-values are significant, <0.0001

	KOOS QoL r	KOOS Symptoms r	KOOS ADL r	KOOS Pain r	KOOS Sport r
Lysholm	0.81	0.82	0.83	0.84	0.76
VAS pain	0.67	0.58	0.65	0.71	0.68

r: Correlation coefficient; QoL: Quality of Life; ADL: Activities of Daily Living; SPORT: Sport & Recreation; VAS: Visual Analog Scale

Statistical analysis

The means and standard deviations for the patients' demographics as well as each of the outcome scores were calculated, and a statistical comparison was made where applicable. Normality of the data was assessed prior to the correlations being calculated. Due to the data not being normally distributed, a Spearman's rank correlation was used to assess the relationship between each of the relevant outcome scores. All calculations and statistical analyses were conducted using Microsoft Excel® (IBM Corporation, Redmond, Washington). P-values <0.05 were considered statistically significant. Correlation strength was defined as weak (0.1–0.3), moderate (0.4–0.6), or strong (0.7–0.9).[24]

RESULTS

In a review of the registry, we identified 79 patients who had undergone surgery for the repair of focal chondral defects. All patients underwent Autologous Matrix-Induced Chondrogenesis, with the application of a Chondro-Gide® matrix, and had preoperative and postoperative scores at one year for the VAS, Lysholm, and all five KOOS domains. The demographic characteristics of the patients are presented in Table I. Of the 79 patients, 62% were male and 38% were female.

The pre- and postoperative mean scores for each of the PROMS are shown in Table II. All postoperative scores were significantly different ($p<0.001$) from the preoperative scores. Additionally, based

on the change in the Lysholm score, and using an MCID of 10.1,[25] the positive response rate was 89%.

All correlations, whether between VAS and the KOOS domains or between Lysholm and the KOOS domains, were significant, at a level of $p<0.001$. These strong correlations between the Lysholm score and the various KOOS domains ranged from a low of 0.76 for KOOS Sport to a high of 0.84 for KOOS-Pain (Table III). Although still significant ($p<0.001$), the correlations between the VAS and KOOS domains was notably lower and would be classified as moderate. The scatterplots for the scores are presented in Figure 1.

DISCUSSION

Overall, the data showed significant, strong correlations between the Lysholm and all KOOS domains. Likewise, the VAS showed a strong correlation with the KOOS-Pain subscale, although this correlation was not as strong as that which was noted between Lysholm and KOOS-Pain. The regression equations that can be determined from these analyses support the ability to calculate a KOOS or Lysholm score when one of them is known. As far as clinical relevance, these results will allow, with a degree of relative confidence, to compare the outcomes of studies of chondral repair that have used either of these PROMs.

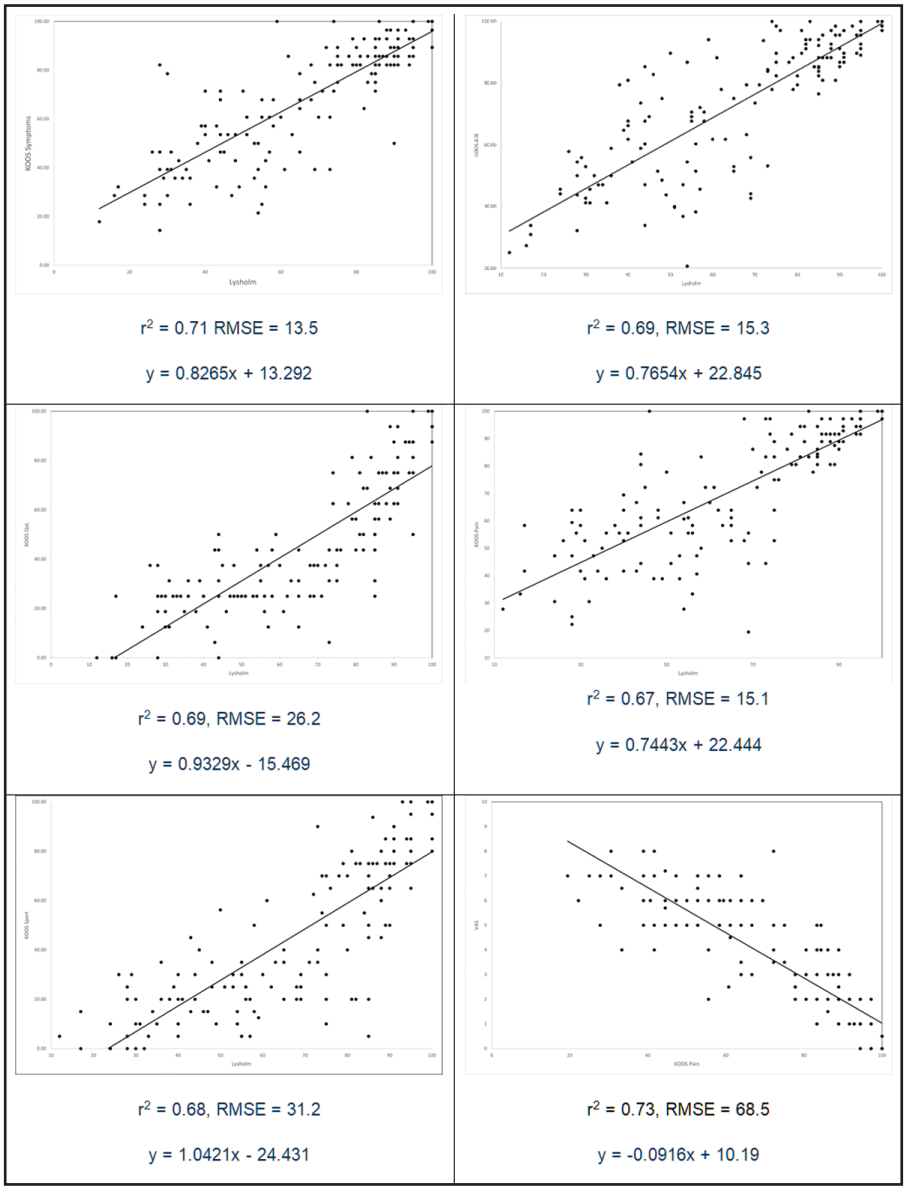

Figure 1. Scatterplot with their regression lines, depicting the Lysholm and KOOS scores. KOOS=Knee injury and Osteoarthritis Score; ADL=activities of daily living; QoL=quality of life; R2=regression coefficient; RMSE=root mean squared error.

The relevance of these outcomes lies in the role that the assessment of patient outcomes plays in real-world medical care. There are a variety of PROMs that are used to assess outcomes following knee surgery. Among the various instruments, the Lysholm and IKDC were reported to be the most responsive instruments over time, while the IKDC may be better suited to detecting changes in function related to higher demand activities such as sports.[26] A recent study had reported substantial variation in the reporting of patient outcomes, with 34 PROMS in use.[27] Certainly, each PROM has a role in measuring patient outcomes, but it may be difficult to assess the changes across various studies, with their different treatment techniques, and develop an overview of treatment effectiveness.

While the IKDC may be one of the most commonly used PROMs, the KOOS and the Lysholm are also commonly administered.[27] Even though all three PROMs are common, a recent study examining the trends in outcomes over the past 15 years demonstrates an increased use of the KOOS by approximately 15%.[28] In daily practice, the use of multiple PROMs can be an obstacle to gathering information as they are time consuming.[29] As just one example, it was estimated that clinical practices spend over 15 hours per week on PROMs, accounting for 785 hours/physician.[30] This represents a value that cannot easily be dismissed. Therefore, by demonstrating the relationship of the scores, it may then be feasible for the physician to document the outcomes with just one PROM, thereby reducing time and expense with confidence that the results can be extrapolated and reasonably compared to studies that have used another PROM score. In our study, we have demonstrated a consistent relationship between KOOS and Lysholm.

Multiple patient-reported outcome measures have been used to assess the efficacy of treatment; however, the most effective measures remain unclear. Effective outcomes are needed to standardize the reporting of various meniscal pathologies to better assist not only patient satisfaction, but the surgeon's decision-making as well. The use of unnecessary PROMs can increase healthcare costs, time, and clinical inefficiency. The absence of guidelines on which pre- and postoperative outcomes to report can also lead to increased bias in the literature, as the

variability of reporting methodology has not been quantified in a systematic manner and there are no comparisons performed between PROMs to determine responsiveness.[29] With the increase in systematic reviews seen in recent years—891 having been published in 2023 concerning the knee—the utility of consistency and relevance in outcome reporting should not be underestimated.

Of importance to patients as well as orthopaedic surgeons, physical function is one of the primary domains of patient-reported outcomes.[31] Such data has been extrapolated—for the past few decades in orthopaedics—as the Lysholm score has been in use since 1982.[32] However, there have been advances in PROM methods, resulting in psychometrically improved questionnaires.[33] Nevertheless, with the availability of numerous PROMs, clinicians will continue to use a PROM with which they are comfortable and can be easily administered. It is not expected that linking studies between different PROMs allows clinicians and researchers to use various PROM scores interchangeably, but the ability to compare outcome assessments between the KOOS, Lysholm, and VAS is likely to be useful to researchers in orthopaedics.

CONCLUSION

Clinician researchers collecting physical function outcomes in research trials can decrease questionnaire burden for patients by selecting one of these two measures while remaining confident that they can still compare their findings to studies that have used the other questionnaire. For those researchers who plan to pool and analyse previously completed studies that had examined physical function with either the KOOS or the Lysholm may now have a means to convert scores using regression equations, which could be a useful tool in meta-analysis. By linking different PROMs, it may be possible to achieve a common metric for outcomes. For researchers who conduct meta-analyses, they could conceivably pool substantially more data related to the repair of focal chondral defects of the knee. STI

AUTHORS' DISCLOSURES

The authors have no conflicts of interest to disclose.

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